Ready, Set, Submit!

>> Kasima Garst: Welcome, everyone, to "Ready, Set, Submit! Grant Application Preparation and Submission." My name is Kasima Garst. I'm a systems policy analyst in the NIH Office of Policy for Extramural Research Administration, or OPERA, in the Systems Policy Branch. Laurie, would you like to introduce yourself?

>> Laurie Roman: Sure. I'm Laurie Roman, I am the Customer Relationship Manager for the eSubmission team in eRA, Electronic Research Administration in the office of Extramural Research. Take it away, Kasima.

>> Kasima Garst: Thanks, Laurie. In this session, we will be discussing how to get your research idea to the NIH for funding consideration. We'll be going through an overview of the grant application process from the finding an opportunity to preparing your application and the steps in submitting an error-free application through Grants.gov to the NIH on time and confirming that it has been received correctly. So to start, this is a screenshot of the NIH Grants & Funding webpage. This is where you can find a link to How to Apply, the NIH Application Guide. This is the How to Apply Application Guide page. As a main overview, this is where you'll find resources related to general application process information, such as the registrations that are needed, how to write your application and format attachments and information about submitting your application including application-submission policies. You'll also find resources, such as annotated form sets and sample applications as well as the application form instructions including filtered instructions for different application types, such as career development, fellowship, training and the multi-project applications. There are two main systems involved in our grant-application process, Grants.gov, and the eRA Commons. Grants.gov is the online portal used by all federal grant-making agencies and their applicants to find and apply for federal grant funding, and the eRA Commons is a system managed by NIH that allows applicants, grantees, and federal staff to securely share, manage and process grants-related information. The key applicant user roles for these systems, for Grants.gov, are the E-Business Point of Contact, or the EBiz POC. This is the individual designated during registration with the System for Award Management, or SAM, who manages grant activities for your organization. This individual authorizes representatives of your organization to perform specific tasks in Grants.gov. They will assign the next individual role that we have listed, the Authorized Organizational Representative, or AOR. This is the user for Grants.gov who has been given this role by the EBiz POC and enables them to legally bind your institution and assume responsibility for adhering to all federal grant administration requirements referenced in the NIH Grants Policy Statement. This is a similar authority to the Signing Official role in the eRA Commons. This user is the one who will actually be signing and submitting the grant applications and required certifications and assurances as part of the submission process. The key roles in eRA Commons for the users are the Signing Official, or SO. This is the individual that holds the authority, again, to legally bind your institution and assume responsibility for adhering to all federal grant administration requirements referenced in the NIH GPS and registers the institution and maintains the institutional profile data. They're also going to be the user that creates and administers user accounts, including additional SO roles and account administrator, or AA, accounts. There's also the Principal Investigator, or PI, role, and this is the individual who is designated as the Project Director or Principal Investigator, PD/PI, of an application or grant. These users perform or delegate tasks such as maintaining personal profile information, checking the application status and checking the assembled application image used for review and performing post-submission administrative functions. They have the ability to access information for their own grants and applications, including summary statements, scores and notices of awards, whereas the SO user will be able to access information for all applications and grants within your institution. There are multiple organizational registrations that must be completed prior to application submission. It's very important that organizations start early, because this process can take 6 weeks or even more depending on other unique factors. So there's the DUNS, or the Data Universal Numbering System. This is a unique organization identifier that is administered by Dun & Bradstreet that is required before you can even register for some of these other systems. Please note that there are plans to switch to a unique-entity identifier, or UEI, within the next couple of years. This will no longer be administered by Dun & Bradstreet, but rather by SAM, or the System for Award Management. This registration with SAM is required to do business with the government and requires annual renewal, so you'll need to make sure that that is in place before you apply for a grant, but also that you renew it annually for any progress reporting and other requirements. Obviously you'll also need registration at the organizational level in Grants.gov because that's required to submit grant applications. You'll also need to be registered in the eRA Commons so that you can do business with the NIH. And it's important to note that the eRA Commons not only requires organizational registration but also that there are key individuals that will need to be registered in eRA Commons such as your SOs, your PD/PIs, as well as sponsors for fellowship applications, candidates for diversity supplement support, component leads on multi-project applications and the primary mentor identified on individual mentor-career- development applications. An additional reminder is that an ORCID ID, or an Open Researcher and Contributor Identifier, is also required for the PD/PI, for individual fellowship and career development applications. This registration is external to NIH, but must be linked to your eRA Commons personal profile prior to application submission. Small Business Administration, or SBA registration, is also required if the applicant is going to be applying for an SBIR or STTR small-business application. There are three primary methods for submitting competing grant applications. Grants.gov workspace, a system-to-system provider solution, and NIH ASSIST. NIH ASSIST is actually a system that's managed by NIH, and it is a system-to-system solution. These three methods will ultimately be the location where you'll compile your grant application data and complete the forms, and then you can compile them all and they'll be routed through Grants.gov to be submitted to NIH. You can think of these three systems similar to how an individual can use TurboTax to complete their tax return forms. This pie chart show a percentage of applications that are submitted using the different systems of submission. The, as you can see, overall approximately 93 percent of NIH applications are submitted using NIH ASSIST or a system-to-system provider, or S2S. The key considerations when you're selecting your submission method in order to prepare your application are to determine what submission method your institution uses, as it's your institution that is actually submitting the application, and also what kind of application you are preparing. Let me get a little bit more into that now. So here are two thought bubbles regarding telling you a little bit more about ASSIST and the Grants.gov Workspace. We don't have a lot of specific information related to the system-to-system providers because there are multiple and they each have their own unique features. However, they will have very similar characteristics to Grants.gov's Workspace and ASSIST in that they will be where you can populate your information and complete your forms, and there will also usually be similar copy features and pre-submission validation features. So, as I mentioned, NIH ASSIST is managed by NIH. It leverages eRA Commons accounts and pre-population features from eRA Commons profile data. Ultimately, you'll be able to track your application status within a single system, and it supports all NIH competing applications, both single-project and multi-project. You'll also have the ability to pull study information from clinicaltrials.gov, and you'll have integrated NIH messaging, such as tips and other system alerts. Grants.gov Workspace is managed by Grants.gov. It requires additional user registrations with Grants.gov. There are no pre-population features from existing eRA Commons profiles because it is external to NIH and the eRA Commons. So that means you must track also your application in multiple systems, Grants.gov as well as in eRA Commons, and Grants.gov Workspace only supports NIH single-project competing applications. This means no multi-project applications will be able to be submitted through Grants.gov Workspace. Regardless of the submission method that you use, your application will be subject to the same registration requirements, completed with the same data items and elements and forms for the individual FOAs or funding opportunities. They'll all be routed through Grants.gov and validated against the same NIH business rules. It's also important to note that the assembled application image will be in a consistent format for review consideration. Individual reviewers will not be able to tell which submission method that you used, and all applications will be tracked in the eRA Commons. There's not a set of universal application forms that can be downloaded from NIH's forms library or individual websites. You must complete the application form package attached to your Funding Opportunity Announcement because it will guarantee that you have the forms that are appropriate for the specific program that you're applying for. The application forms are accessed using your chosen submission method, and we'll talk a little bit more about that on a future slide. So now I'm going to turn it over to Laurie as we talk a little bit more about the application process.

>> Laurie Roman: So right, I'm going to basically step us through the eight major steps that you need to complete to successfully submit your application to NIH. The first step is finding a Funding Opportunity Announcement. We recommend going both to Grants.gov as well as searching the NIH Guide for Grants & Contracts. Obviously, when NIH's grants are going to be found on the NIH Guide for Grants & Contracts, but it's really advantageous to search Grants.gov because first they also have a very robust search capability, and you have the added benefit of returning opportunities for other funding agencies. For example, DoD, Department of Defense, has a number of opportunities that support breast cancer research. I'm going to turn it back to Kasima to go through the Funding Opportunity Announcement, because a lot of this is sort of policy-driven.

>> Kasima Garst: Thanks, Laurie. So the Funding Opportunity Announcement, or FOA, text contains a lot of information related to how you can apply, what eligibility is related to a particular funding opportunity and also the various review criteria and other things that you need to consider when you're preparing your application. It's very important that you carefully read the full announcement. This first section, in part one in the overview information, includes the participating institutes and centers of NIH that are participating in the Funding Opportunity Announcement. It's very important that you check to see if you are aligned with some of the goals and objectives of these institutes, as well as the related notices section, which is very important to check for this is where you'll find notices of correction, notices of information, policy notices, as well as notices of special interest, or NOSIs, that may be targeting that funding opportunity for submission. It's best to remember, "Check for fit before you submit," to make sure that you are eligible and that this is the right opportunity for you to apply. The next key section is the FOA key dates. This is where you'll find application due dates and the dates associated with other parts of the application submission and review process. As you can see here, the due dates section will include either specific due dates for application submission or will link to the standard due dates webpage. And as you can see here is a screen shot from that page showing the standard due dates for three cycles for new R01, U01, and K-Series applications. Note that the table will indicate if there are different standard due dates depending on your application type, whether it is new, revision, or renewal application. Next in the Funding Opportunity Announcement is the application and submission information sections, as you can see here. The key things to point out are the link to the application guide. This is that same page, that How to Apply - Application Guide page I had pointed out earlier in the presentation. You'll also have links to ASSIST and Grants.gov Workspace, if applicable. This is where you'll actually go to access the application forms package for the Funding Opportunity Announcement. As you can see, we don't have links to the independent system-to-system solutions to prepare those applications because of the different S2S providers, so you'll need to work with your institution to determine if you are using an S2S solution and how to access that information. But ultimately you'll be accessing the same application forms package regardless of the submission method that you are using. I note that Grants.gov Workspace is only applicable if, for example, you are not doing a multi-project application, as those are not going to be able to submit through Grants.gov Workspace. The next key section for point out is the table of contents, and part two, in particular, related to to the full text of the Funding Opportunity Announcement. There are some key sections that you really want to pay attention to as you are preparing your application and determining if this is really the right Funding Opportunity Announcement for you. Section one, the funding opportunity description section, includes information about the program, and this is where you'll really want to check and make sure that this is the right fit for your research idea. Section two includes the award information. This includes the application types that are allowed, new revision and so on, as well as the clinical trial allowability indicator. Section three, or the eligibility information, includes eligibility information related to organizations and the PDPI. So you'll want to make sure that your applicant organization is actually an eligible one for the Funding Opportunity Announcement. Section four, application and submission information, includes any FOA-specific submission instructions, particularly as it relates to the individual forms themselves. For example, you'll often see extra information here as it relates to the requirements for the research strategy. Section five, application review information, includes criteria that will be used to evaluate your application for scientific and technical merit through the NIH peer review system.

>> Laurie Roman: Hey, Kasima, this might be a good place to tell our listeners about some recent changes to NIH's policy regarding responsiveness to PARs, which are program announcements with special receipt dates or review criteria, as well as PASs, which have ... S is for set aside funding.

>> Kasima Garst: Great point, Laurie. Yes, recently, this past June, NIH issued NOT-OD-20-114. This was a Guide notice that announced that there will be changes to how handling applications submitted in response the PARs and PASs. Unlike parent announcements that are broad FOAs allowing applicants to submit investigator-initiated applications, PARs and PASs highlight areas of specific scientific interest by one or more ICs. As a result, now PARs and PASs may chose to describe within the Funding Opportunity Announcement criteria that would make an application non-responsive to those specific scientific interests. So you'll find information related to any non-responsive criteria in section one, that funding opportunity description section of the FOA. It's important to pay attention to this when it's located in that section in PARs and PASs because applications that are deemed non-responsive will be withdrawn from review consideration. Great point, Laurie.

>> Laurie Roman: Thanks, so now let's get back to our planning steps. So this is one of my sort of favorite and important take-home messages. So my dad, one of his favorite acronyms was PATSA, which was not pasta with a Boston accent, but Plan Ahead to Stay Ahead, and I can't emphasize enough that you can never start too early. So as soon as you've got your Funding Opportunity Announcement, the next thing you need to do is identify your team members. Verify that all of the registrations that Kasima mentioned earlier are in place. And again, as SAM requires annual renewal, that it's active. You're choosing your submission method and the first thing that you're going to do in that regard is contact your sponsored research office, find out how they want you to submit. Determine who is going to be doing what. Who is going to be responsible for the science? Who cares about the money? Who is going to do data entry? Who is going to give you the most beautiful micrograph pretty picture? And then again, make sure that everyone is aware of the process of both internal and external deadlines. And then make sure that you have people in place, not getting on a plane and going someplace lovely, though not so much these days, that's going to be able to deal with eRA warnings and verify the application in eRA Commons following submission. So here is a screen shot of what the initiation page looks like for ASSIST. At this time you would have to enter your eRA Commons username and password, and then that will take you to the initiation screen where you would put in that Funding Opportunity Announcement. The next step is building your team. So we've already talked a little bit about pulling everyone in that you think will be involved. Both ASSIST and Workspace have specific tools called Manage Access and Participants, respectively, that allow you to grant access to other individuals to work on the application. And you can control what sections of the application that they can see and whether they have read or write privileges, and you can, effectively, as well, block them from seeing things like the budget. For anyone to be given access to an application, they will need eRA Commons credential. In addition to actually working on the application, Kasima has already mentioned that you need to have individuals' Commons accounts if they will be serving as the PD/PI of the application, for multi-project applications, component leads will also need to have eRA Commons credentials. Sponsors on fellowship or F applications as well as candidates for diversity re-entry supplements, both of these will also need to be registered in the eRA Commons, which is basically an affiliation process since it is the institution that does the primary registration. The primary mentor on individual mentor career development applications also will require a eRA Commons credentials. This is one of the great tools that we have available, and I'm now looking on the right-hand side of the slide, and this is an annotated form set. These come in a couple of different flavors. We have them for single-project, multi-project, small business, and this is a step-by-step walkthrough that shows you all of the required fields that must be completed in the application as well as some useful descriptors. On the left-hand side of the slide is a really important hierarchical arrangement. So Kasima told you a little bit about where you can find links to the How to Apply Guide which is, again, a step-by-step, 100-page document of every single form and every single field. The next step, as we've talked about, is information that's actually contained within section four of the Funding Opportunity Announcement. This tells you specific information that may need to be in a justification or a specific attachment that must be included. I'd like to say that we were perfect, but we're not. We make mistakes. And so, you then also need, and most important, to look at notices in the NIH Guide for Contracts for updates to Funding Opportunity Announcements as well as Notices of Special Interest which highlight specific areas of science that are of interest to one or more institute. These Notices of Special Interest, or NOSIs, will point to parent announcements or parent supplements to use to prepare the application. So the hierarchy, again, is starting at the instruction guides, those instructions are superseded by the FOA and anything in the notice will supersede instructions in the Funding Opportunity Announcement, so important facts to remember. Next, a little bit of a few quick comments on application attachments. You must use simple PDF-formatted files for all attachments. There is no value to password protect them and give us the password in a cover letter because our systems don't read the cover letter. So disable, please, all security features such as password protection. You must keep your file names to 50 characters or less, and file names must be unique within an application. These are two of the biggest sources of errors and system-related errors that we encounter. Use meaningful file names. If the Funding Opportunity Announcement tells you to name something "My Favorite Attachment," please name it "My Favorite Attachment" because that will be a key tool that we use to highlight that attachment in the bookmarks of the assembled application. Please do not include headers and footers because guess what? We put on headers and footers, so we really recommend using headings such as significance, innovation, approach. Those are really things and really good things to add and really help the reviewer work their way through your application. Make sure you follow the specific page limits as well as guidelines for fonts and margins and hyperlinks and URLs, and there's some recent guide notice that's come out about hyperlinks and URLs. Those last three things, if you fail to follow page limits, fonts and margins and hyperlinks, your application may be subject to a withdrawal. This is an issue of fairness in terms of keeping things consistent in terms of what is expected for an application. Okay, we're coming in on the end, here. Step six out of eight, finalize your application. The key is, and we've broken it down into, again, the language in ASSIST and Workspace, but you want to run a pre-submission validation check. These are business rules, and what we're going to do is when you invoke that pre-submission validation check, we're going to do a quick rule check for every single form that is in that application to make sure that required fields have been completed. It's also really important that you generate a pre-submission application image to see that the application is assembled in the format as you expect it to be. So again, checking for the placement of photographs and images, that they all look as you expect them to. And then, take any additional steps that you need to prepare for submission. So now we're honing in at the very end, submitting your application, so you're going to follow the specific steps that are consistent with your submission method. So in ASSIST, you're going to update the submission status, which will then present to the AOR where they can then enter their username and password. As Kasima mentioned, regardless of submission method used, all applications will be routed through Grants.gov and it is the Grants.gov timestamp seen here in a red box that determines your on-time submission. This is in Eastern Standard Time or Eastern time. We know how to do the math. When you go to put in a change corrected, and we'll talk about that in a minute, it is the Grants.gov tracking number here, seen under Grants.gov that you will be using for those changed-corrected applications, and I do want to call your attention to agency. So no happy dancing until you see the agency tracking ID. In this case it's that 4484140. That is your unique identifier, also known as an accession number. If you click on that, this is what, again, Kasima mentioned, you can track your application in a single place in ASSIST. This will loop out to the eRA Commons where you can view the assembled grant image that will be available to the reviewers. On-time submission: Deadlines are 5 o'clock local time, so if you are in Anaheim, California, it's 5 o'clock Anaheim, California time. If you're 5 p.m. Heidelberg, Germany it's 5 p.m. Heidelberg, Germany. We know how to do the math. All registrations and SAM renewals must be completed before the deadline. There is next to no sympathy for incomplete registrations before a due date. Applications must be free of all federal systems-identified errors, and those are at both Grants.gov and eRA. NIH late policy does not allow you to make corrections after the deadline. So NIH strongly recommends submitting early to allow time to correct any unexpected errors or submissions. For those of you in sponsored research offices, our favorite mantra in this regard is, "Early is measured on a calendar, not a clock." So the last step is tracking your application. We've mentioned that the eRA Commons status is an integral part of your submission process. This is where you can verify that your application has passed all validations and has been picked up and assembled according to NIH policies and standard operating procedures. The individuals that can check the status in Commons include the signing official, the administrative official, the PD/PI and delegated assistants. We do send e-mails to both the AOR, SO and PD/PI, but recognize that it is an imperfect delivery system and so be proactive and actively go in, log in, and check your Commons for the status of the application. Again, to highlight, errors stop the application from processing and must be corrected. Warnings do not stop the application and you can correct them at your discretion. There are some warnings like $500K, which is that you're not allowed to submit an application without prior approval if your budget is $500K or more for certain activity codes. So again, if you have gotten your approval, happy dance. You can certainly ignore that. If you have not gotten prior approval, you can expect someone will be sending you an e-mail in a couple of days. And then to correct errors, you want to then make sure that you do those corrections on the copy that you have in either Workspace, S2S, or ASSIST. You're going to then change the submission type to changed corrected. You're going to enter the Grants.gov tracking number that I highlighted before in 4C, and then when you submit the application it will, again, get routed through Grants.gov. Again, this process has to take place before the deadline. Reviewers have no access to how many times you've submitted applications with errors and warnings. So don't worry about that, get the application in and get it in on time. Again, a good mantra is if you can't see it, we can't see it, and we can't review it, and we sure can't fund it, so really important to track it through this last step to make sure that you see a grant application in eRA Commons. And this is the appropriate slide. We do put this application together in a really pretty view. We insert the PD/PI's name as well as a header and footer, so we paginate the application. We generate a table of content and bookmark important sections of the application. For multi-project applications we also create a number of summary tables, and we post this to the PD/PI's eRA Commons account. So applicants have 2 business days, so the weekend doesn't count, to view the application image before the application automatically moves further forward for further processing. And these are the two -- So in ASSIST you need to go in and view submission status. In Workspace you need to log into eRA Commons. So the SO has the ability to reject applications within the 2-day viewing window to prevent it from moving forward. And then, of course, you can submit that changed corrected before the submission deadline. Submission complete. So if you don't reject the application within those 2 days the application goes forward to the Division of Receipt and Referral or to the IC, depending upon the Funding Opportunity Announcement. Any subsequent application changes are subject to the NIH late policy, and I will turn it over to Kasima to finish up.

>> Kasima Garst: Thank you so much, Laurie. So the last thing we wanted to highlight for everybody is obviously Laurie has talked about the application checks and the pre-validations, but we really wanted to highlight that there are multiple rounds and levels of checks and validations that are part of the submission process. Some are automatic system validations, while others are completed as part of a manual review. Applications will first encounter system validations from Grants.gov. These are primarily Fed-wide level requirements and some higher level validation such as checking if the FOA and application forms package are actually active, as well as virus checks and that the submitter has the appropriate AOR role for the applicant organization. Applications will also encounter system validations from eRA systems based on agency level requirements, so these are requirements that NIH has for our application forms, such as appropriate credentials, eRA Commons credentials, for the PD/PIs on the senior and key personnel forms, as well as that there is a DUNS number for the primary site on the performance site form, that the attachments are in the appropriate PDF format, and that we adhere to page limits that are specified in our table of page limits webpage. The application will also go through a round of manual evaluation after submission through the system. This stat will be basically for requirements that NIH has both at an institute as well as the IC and program level that are not as easily validated at a system level. So this is looking at things such as overstuffing, that on time submission that Laurie mentioned, and then whether or not you adhere to the Funding Opportunity Announcement-specific instructions. So even though the application itself may get in the door, if the application is found to not meet other requirements that were specified in the Funding Opportunity Announcement, an application may still be withdrawn if it does not pass these checks. So I hope that you learned a lot in this presentation. We know it was a lot of information, and we also wanted to just provide you with resources to help you if you have any further questions. We have contact information for the help desk. It's important to note that if you have a Grants.gov technical issue or questions you really do need to contact the Grants.gov help desk. There's also information for the eRA service desk. One important thing to note is that if you are having technical issues at Grants.gov, and particularly as it relates to application submission, it's often very helpful to still contact the eRA service desk so that we can be aware of any potential system issues. Laurie, is that correct?

>> Laurie Roman: Absolutely.

>> Kasima Garst: Thanks, yeah. It's very important because that way if there is a technical issue, and there's more information about this on our How to Apply page about system issues, that we have it documented. And lastly, we have some online resources and websites, the NIH Grants and Funding webpage, the Application Guide, that really awesome annotated form sets resource and also some additional information if you are planning to prepare your application using ASSIST. We also have some great LISTSERVs that you can subscribe to if you are interested in learning more, and it's also a great way to stay connected and to get information, particularly as we are making various changes and system updates related to eRA Commons, ASSIST, and various e-submission topics. Thank you all, again, for your time, and I hope you enjoy this presentation. Thank you, everyone.