Preparing for Electronic Grant Application
Morning Session Transcript

Chuck Selden:
Good morning. I'd like to welcome you all to this training on 'Preparing for the NIH Electronic Grant Submission.' Welcome everyone in the auditorium here at Natcher Auditorium on the NIH campus, and welcome to all of you watching on the NIH videocast, both staff and those in the applicant community.

I'm Chuck Selden. I'm the NIH extramural staff training officer. I'm responsible for continuing education for NIH staff. Our other speakers today are Megan Columbus, the NIH program manager for electronic submission, and Marcia Hahn, the director of the Division of Grants Policy.

Our agenda today has four parts. We first have an overview of the electronic submission process, and then we'll walk you through the SF424 form. This is the new application form. We'll have a panel of experts addressing the meatier questions, the lessons learned in one year of receiving grants electronically. We've successfully received about 20,000 grant applications, so the system is new and it works. And then we'll have a question and answer period with the same panel of experts.

First, I'd like to outline some take-home points. These are the major differences between submitting electronically on the new form, the SF424 (R&R), and the PHS 398 form. First of all, before, you'd just send in your grant application after finishing it and having it signed by your business official. Now you have to pre-register. Both the investigators have to register and the institutions have to register. Do this well ahead of time. You can do it today if you haven't registered already. Then for the grant form, instead of the same form being used for all of the mechanisms, you have to download and use specific application forms to match the mechanism to which you are applying, so that means that all grants submitted now have to be in response to a Funding Opportunity Announcement, and it has to match.

The application is not written from start to finish, like in the old days where you put the whole thing on your screen or even into a typewriter, I remember that, but you -- after downloading the application from the web, you fill in parts of the form on the parts of the form itself and you attach files, Portable Document Format files, as many as eighteen of them, so this is -- this is quite different than before.

You're not done with the application process until it's been sent in to Grants.gov, which then transfers it to the NIH after doing some validations. The NIH does validations and then puts it up onto the eRA Commons, where the investigator and business official can look at the completed and assembled grant application. This is the way the application will look to the viewers, and this will be the first time, again, that you can see the completed application. Then, once you've looked at it, you'll have two weekdays to look at this, then you verify that it's ok, and now the process for application is completed.

We'd like this to be interactive. You can submit questions as they come to you on index cards, or electronically if you're in the videocast audience. On the videocast page for this event, when you go to "Today's Events" and you come down to the section for this event, down at the bottom of that little section it says "live event recording form." You click on that, that opens up an email, and you can type your question in there and send it. And we have a computer and printer here and will be bringing those questions up to address to the panel. And so that email address is nihelectronicsubmiss -- that's without the "ion" -- @mail.nih.gov. Now to give you an overview of electronic submission, we have Megan Columbus.

Megan Columbus:
Thanks, Chuck. Alright, thank you for joining us. Today we're going to be talking about the new process for submitting applications to NIH, and this is a fundamental change in the way NIH has done business and the way that applicants have interacted with NIH to submit their grant applications.

Now that involves new forms and a new process. Fundamentally, our policies about grants have not changed. Our late policy has not changed. Our policy about submitting corrected applications to the Scientific Review Administrators has not changed. The policies about all kinds of post-award administration reporting and all those things haven't changed. So what we're just doing is changing the upfront process to take advantage of federal-wide forms and the twenty-first century in technology. Fundamentally, it's still all about the science.

You're all taking a great first step. The most important thing, I think, to get on board with this, is to understand the instructions, to understand the process and the new forms and to familiarize yourself with them. Once you do that, you'll find things flow pretty well.

So the president's management agenda, and this is being supported by OMB, which is the Office of Management and Budget, is requiring that all agencies make available opportunities to be applied for through Grants.gov, which is a central portal for all the federal government to apply for and find grant funding.

By the end of 2007, NIH plans to do two things. We plan to require electronic submission of the grant applications and we plan to do it on the new Standard Form 424, "Research and Research-related," R&R form. Marcia Hahn will tell you a lot more about this form in a few minutes.

This isn't new for NIH now. We've started a new bill with the small business community, with our small business research grants. Since then, we've processed over 18,000 electronic applications, and we've transitioned sixteen different research programs in anticipation of the R01, which of course is one of our most important programs to NIH.

These are what we've transitioned to date. You'll see that the transition date for each of these mechanisms is on this slide. This means that, as of that date, all applications coming in for that date are required to come in electronically on the new Standard Form 424 (R&R). So if we look at what's coming up in 2007, we'll see that the biggie, and what most of you are probably very interested in this room and watching on videocast, is the R01. The new receipt date -- the new standing receipt dates for R01s, because there is a change in our standing receipt dates that's effective January 3rd , I believe, of 2007, that for any R01 coming in for the February 5th receipt date and beyond will require the new forms and submission through Grants.gov.

You'll notice that NIH saved the most challenging for last, so all of the complex programs don't transition until the end of 2007, and we hope that we can do it then. There's still some doubt. And you'll see the Career Development and the Fellowship and the Training programs are towards the end of the year as well.

We've been working very hard to prepare for the R01s. We expect 4,000 to 5,000 unique R01 applications in January. We've done extensive risk analysis and capacity planning, and we've made sure the help desk is well-staffed and well-informed. We've worked out a lot of the kinks along the way, and, in fact, we've already accepted R01 applications as part of a pilot for Multi-PI applications. And Marcia will probably talk to you a little bit more about the fact that Multiple-PIs will now be accepted on the R01 grant applications from February 5th and beyond.

So let's talk a little bit about the process. I'm going to try and be walking you through, in a fairly explicit way, how to prepare to apply. That's to make sure that you're registered, you have the appropriate software, those kinds of things. How you find the opportunity and download an application package. As Chuck mentioned, one of the take home points is, this is very important because in the Grants.gov model — which NIH didn't design, we just play a part of — every application must come in in response to a Funding Opportunity Announcement, okay? Which is a little bit different than we've had in the past, and we'll show you how we've developed a way to make sure that we continue to accept unsolicited applications and those kinds of things.

Marcia will walk you through preparing an application and the new application form set, and she'll highlight some of the differences between the 398 and the new 424 (Research & Research-related) application. We'll talk about submitting to Grants.gov. One thing you'll note is a fundamental change in your applicant organizations is, who's the last person to touch that application? It's no longer the Principal Investigator. The Principal Investigator is to send the application to the central grants office, and the Authorized Organizational Representative, that's what AOR stands for, is the one who must submit the application on behalf of the institution, and we'll talk more about that as well.

We'll walk you through making sure the application is complete, because, as Chuck mentioned, it's not complete until we see the application in NIH's system, which is called the eRA Commons. So even once it's submitted to Grants.gov, you still have final steps to take to ensure that NIH received that application. You'll check the application to make sure that the image of the application is as you intended and true to the information that you sent us, and then your submission will be complete.

So let's talk a little bit about -- I keep mentioning Grants.gov and the eRA Commons. These are two distinct systems that are managed by two distinct organizations. NIH does not manage Grants.gov. Grants.gov is the equivalent of a central post office for the federal government for all research grants. It happens -- HHS, the Department of Health and Human Services, happens to be the managing partner. This is outside of NIH, and NIH works closely with Grants.gov, and tries to influence how Grants.gov approaches the application form and its process, but we don't have full control over that.

The eRA Commons is NIH's electronic system. It's a system that goes out to Grants.gov and retrieves your application once it's been submitted, and it's a system that you interact with directly to check the status of your application, to do post-award reporting, to view your application image, that kind of thing. The eRA Commons, as well as this electronic process, is used both by NIH and some of the other HHS components like AHRQ or portions of the Centers for Disease Control.

So let's talk about registration. Registration is kind of the upfront work. In all honesty, I think it's actually -- the Grants.gov registration part for the institutions is actually one of the harder things to do in the whole thing. Luckily, Grants.gov registration is a one-time-only process for an institution. This is important. It can take two-to-four weeks. I would encourage you to leave in even more time. There are multiple steps in this. Many of the organizations that are applying to NIH have already done this step. I would certainly recommend you go back to your institution to make sure that this step has been taken care of for your institution. But it involves multiple things. It involves making sure that you obtain an EIN number from the IRS. It requires a DUNS number from Dun and Bradstreet. It requires registering with CCR, which stands for Central Contractor Registration. These are people that take care of registering organizations to interact electronically in all of the federal government. And then, it requires telling Grants.gov who has signatory authority in your institution to be able to submit a grant application on behalf of your institution. And organizations can have multiple authorized organizational officials within the organization, so it's not -- it doesn't have to be a complete bottleneck.

Especially if you're a small business, I would recommend starting very early with this process. The grantee organization also has to register for the eRA Commons. So if you're an organization, you have two registrations you need to complete. You need to finish Grants.gov registration and finish registering yourself in the eRA Commons before you submit a grant application, which means that you need to have your username/passwords for each of those in hand before you submit.

The eRA Commons registration is also a one-time registration. The eRA Commons has been around for longer than Grants.gov, so you need to register what we call your Signing Official. Your Signing Official could very well be the same person who is your Authorized Organizational Representative for Grants.gov. Again, you can have multiple

Signing Officials for your organization, and again, these people are people who have signatory authority to be able to commit the organization.

An important fact is that, as an institution is giving privileges and setting up accounts for users within the institution, that Signing Official has to have one account, and an organization where the Signing Official is also the Principal Investigator, you need to make sure that you assign two separate accounts for that person, one as a Signing Official and one as a Principal Investigator.

The eRA Commons registration may be done simultaneously with the Grants.gov registration. They don't have to be done sequentially, but you really need a DUNS number from Dun & Bradstreet for both. And that's really easy to get. It's a telephone call or email and can take a day or two. Again, allow a minimum of two weeks in advance to complete this registration.

If you are a Principal investigator or an institution registering Principal Investigators, know that in order to initially register, a Principal investigator must work with the institution and the institution must initiate the registration for the Principal Investigator. If you are a Principal Investigator (PI) and you have an account to use for Internet-Assisted Review because you've done reviews for NIH in the past, you will still need to register through your institution in order to get full privileges in the eRA Commons. And what's important is to know that for a PI, that you have one account. Once an institution has established your account and you've completed the process of setting up that account, that account then follows you with you throughout your career. If you are applying through multiple organizations, that's not a problem. It just means that the second organization, or if you just switched jobs, your new organization, just needs to be sure that they affiliate your account with their organization.

PI registrations are much quicker, but still leave four to five business days to complete. There's a process on the NIH side where we work with you to reconcile which applications that you've had in the past at NIH really belong to you, so we can make sure that your account is really reflective of your past history at NIH.

Okay, so you've finished registering with Grants.gov, you've finished registering with the eRA Commons, PIs have worked with our institutions to register with the eRA Commons -- now you need to be thinking about what software you need on your computer. Most of you will be using -- Grant.gov's developed a downloadable forms solution. That means that you'll be going either through the NIH guide or directly to Grants.gov to find a Funding Opportunity Announcement and download an application package specifically from that Funding Opportunity Announcement to your local machine, and saving it on your local machine for you to work on until you submit it to Grants.gov. In order to use this downloadable forms solution, you'll be using a PureEdge viewer, which is software that's free at Grants.gov. And I'll talk a little bit more about that.

There's another option for institutions, and some institutions are doing this, which is to develop system-to-system transmissions to NIH -- I'm sorry, to Grants.gov. Which means that they have built their own system to collect the same data elements that are on the Standard Form 424 (R&R), and they're sending those data elements directly to Grants.gov, not using this form. So the one thing that you're going to hear me say multiple times during this presentation, and I'm sure Marcia will reiterate as well, is that PIs should contact their central grants offices early to find out what solutions those offices have put in place for their institution, and what new processes have been put in place.

So beyond the PureEdge viewer, which you go to Grants.gov and download — it just takes a few minutes to download —you'll also need PDF generation software. If you're a Mac user, that's easy, it's already embedded in your Mac. If you're a PC user and you don't have a commercial, off-the-shelf product to do this, there are some free options that are available on the Grants.gov website, or low-cost options depending on how many bells and whistles you want.

Now Mac users, this has been kind of a bone of contention for NIH and for our applicant community. The academic community uses Macs more than virtually any other community that applies for grants in the federal government, and I've actually been working hard with Grants.gov because the PureEdge viewer that I mentioned, in its original incarnation, was not compatible with Macintoshes, which meant that if you're a Macintosh user, you have to use a Citrix server with your Macintosh, that NIH gives you access to, in order to use that software on your Macintosh. You'd have to use PC emulation software or something equivalent to that.

Now, however, IBM, who owns this PureEdge viewing software is coming out with one that works on your Macintosh. Now, there is an early-release version right now on the Grants.gov website that has all kinds of very scary caveats on it, and I recently tested a later version that I believe that Grants.gov will be releasing this month, hopefully in the next couple weeks, that is a much improved version that will work on the majority of Macintosh computers and doesn't have the same limitations. So I'm pleased to say that this should not be as big an issue as it has been in the past. We'll continue to host Citrix servers, and so we'll continue to provide that solution. And the one thing to keep in mind is that, if you are a PI who has a Macintosh, remember that the entire Research Plan you're writing in your word processing software on your computer, it's not part of the form when you write it, you're just writing the way you normally would. You're then converting that text document into PDF format, and then you're going to attach it as multiple attachments to the application form. So actually putting the form together, when I tried it, took about an hour for me to do, once I had all my text attachments completed and ready to go.

Again, as you prepare to apply, this is really going to be a very tight partnership between PIs and the central grants offices. Institutions will need to determine how your internal review and approval process works with the electronic grant applications. You'll need to determine how you're going to share applications in progress, whether you need to put in place central servers to manipulate the files and save them and share them, or what your process will be. You also need to decide how you're going to manage that queue at this office of sponsored research. So, you have a lot of applications that are coming due on a given day, you're going to need to figure out what your internal deadlines are to get those applications from your investigators to make sure they can all get in on time.

This slide talks again about what your options are for submission, and again, this is an institutional decision on whether they're using a form-based solution, system-to-system transmission, or a third option, which I've not yet mentioned, which are commercial Service Providers. So there are companies out there that institutions can buy the software from the companies or they can ask the company to support a single application submission. These commercial Service Providers offer an array of options in terms of comprehensive systems that interface with your human resources and your financial data systems to -- things that can really just work on one application because you need a little bit of assistance. They -- I believe that there are some fliers out front from some of our commercial Service Providers, and they're on the Electronic Submission website, which we'll give to you a little bit later, you'll find there's a link to those companies who offer those types of services.

Okay, so you've finished preparing to apply. So you've made sure everybody's registered in Grants.gov, the institution's registered in Grants.gov, the institution's registered in the eRA Commons, the PI's registered in the eRA Commons, you've got software on your machine so that you can download the applications appropriately and prepare your application. Now it's time to find a funding opportunity.

Okay, so you remember, Chuck started us out. This is a very fundamental difference. You must find an opportunity, and apply for it in the new [process]-- download the application that's specifically linked to that opportunity, use that application, and apply directly to that particular Funding Opportunity Announcement. NIH will continue to post Funding Opportunity Announcements. These are Requests For Applications; these are Program Announcements. We'll continue to post them in the NIH Guide [For Grants & Contracts], as we always have. They'll also be posted, and we've been doing this for at least the last year, on Grants.gov, you can search for it either place. I happen to find it a little bit easier, if you know you're looking for an NIH solicitation, to find it in the NIH Guide. You can find the NIH Guide at this website.

Now, for that investigator-initiated -- what used to be called "unsolicited research," we completely still want these applications. So what we've done is that we've created very general solicitations that capture a broad range of what everything NIH does and any particular -- for any particular mechanism. So for mechanisms that -- like the R01 -- that we have traditionally accepted unsolicited applications, we still do. What you'll need to use is these Parent announcements. There is a single Parent announcement, for example, for an R01. There's a single Parent announcement for R03, a small research grant, or an R21 which is Exploratory/Developmental. We've developed a website that provides you those Parent announcements.

You're on the Office of Extramural homepage -- Office of Extramural Research homepage, excuse me, and under "Funding Opportunities," you'll see Parent announcements listed. You can also search in the NIH Guide using the word "Parent" in the title. There's a number of ways you can get to them. This is probably the easiest.

So what you'll do is you're searching for a Funding Opportunity Announcement. You'll go to the Funding Opportunities page -- so if I go back one slide you'll see to the top left-hand corner is Funding Opportunities. This is the NIH Guide for Grants and Contracts. You can search. You'll notice the Parent announcements are also on this page at the bottom of the page. You can enter your search criteria. You'll see the title on the top line, here, is "Research Project Grant," and in parentheses you'll see "Parent R01." All of our omnibus solicitations, umbrella solicitations, whatever you want to call them, they're called Parent announcements, and so that's it. So for the R01s, its number is PA-070-70. Okay?

You click on the Funding Opportunity Number to open the announcements. What you'll see is that within the announcement -- and we've just blocked off this little tiny portion,-- the announcement which you should read very carefully, by the way, because it does give you instructions for applying within that announcement, but it takes you directly to -- this button in the announcement takes you directly to the Grants.gov link to download the application instructions and the application forms. So you'll see how the forms are tied specifically to the Funding Opportunity Announcement.

Once you click on that download button in Grants.gov, you're going to get to a screen that looks like this. There's a couple things I want to point out about this screen. One is, please take the time to sign up to receive notification of changes to that Funding Opportunity Announcement. If we have to make some change to the application package it's very important that you know that that change has been made, because Grants.gov won't accept that old application package if you use a new one. We need to have a way to know who's interested in applying for that particular solicitation to be able to tell you about the change.

And in the bottom left-hand corner, you have "Download the application instructions," which is the Application Guide, which is an incredibly important document, especially your first time through. I would urge you to look at it carefully, and download the actual application package. When you download the application package, and you hit that button, remember at this point you have to have PureEdge loaded on your machine -- the PureEdge Viewer that was free from Grants.gov, it must be loaded on your machine -- and you'll see that it opens, once you hit download, it opens this application package directly. The opportunity title and the agency and opportunity number are pre-filled. The first thing you'll want to do is hit "save" to save this locally on your computer sitting at your desk. At that point, you are offline from Grants.gov and working on your computer at your desk.

Just a heads up, when you hit "save," you will get a warning about saving the package, and that warning is because you have not yet completed the entire application form, so

it's just a heads-up that you're saving a package that is not yet completed, and that's perfectly okay. Oops -- sorry.
So now Marcia Hahn -- now that you have this application package sitting on your desktop -- is going to talk to you about the application package, how you manipulate that, and how you get it ready for submission. Thank you.

[applause]

Marcia Hahn:
While I'm getting set up here, this will be your opportunity to get one of your other handouts out along with this slide presentation. You're going to want to take the handout out that is actually a sample application package. When we get to walking through the various components, it's going to be much easier for you to use that handout rather than to see the slide that actually shows that particular component, so you're going to want to have that handy as well.

My part of the presentation is going to take you step-by-step through each of these data components. While we're going to talk about the components as sets of data for the PureEdge form, keep in mind, if you're using a System-to-System system to send in your application, you're going to want to become familiar with these various data elements as well. The data elements are the same regardless of which way your institution is going to actually transmit that information to the NIH.

So let's talk a little bit about some general features here. You've already heard some of this. We're going to reinforce these things over and over throughout the morning because some of these are important -- significant changes in our business process that need to be reinforced. And so, for NIH, a complete application will include a combination of the R&R form components that we're going to walk through, as well as some agency-specific components which we have labeled the PHS 398. We couldn't call them NIH because some of the other agencies from the Department of Health and Human Services are using them for their packages as well.

As you've heard already, you must complete the application that is using the package attached to a particular Funding Opportunity Announcement (FOA). A lot of the information is actually pre-filled from that FOA, and so it's all connected.

You cannot use any of the sample packages that we've put on our website. Those are there just for you to look at and get a look and feel, but don't try to use those for any actual grant application, please, because they will not go anywhere. They won't -- when you try to submit them they will not come into the NIH. They're only there for you to test and to kick the tires with, type of -- take a test drive. You will hear, as you heard Chuck even say as one of the take-home messages, the new way of doing -- of completing an application now -- much of what you complete is actual data-entry in very -- in specific data components, but then an awful lot of the application is appropriate attachments, and we're going to talk about a little bit more of those as we get to each of the components. The first set of components that we're going to walk through are those actually in the SF424 (R&R). One of the features of the R&R, since this is a federal-wide data set, you are going to become familiar with these particular components for any federal agency that is using the R&R. So these are the common data components that are not just NIH but that the NSF is using, and the Department of Energy is using, and USDA is using. So you will become familiar with these components through this session, but you will be able to use this information as you apply to other agencies as well for any of those that are here in the R&R data set itself. So we're going to walk through those, and then we'll also walk through the 398-specific data components, because at the end of the day when the R&R was put to bed, NIH still had a number of data elements that were needed for our biomedical research portfolio, and so that's why we've also developed some PHS 398-specific in order to maintain our business processes and our data collection needs that are unique to the NIH.

You've heard about how we've got data as well as multiple attachments. Most of the attachments that we're going to talk about are text attachments, and for NIH applications, all text attachments must be converted to PDF. We will not accept any other type of text attachment, and you can create those text attachments using any type of word processing software, and then convert them to PDF before attaching them to the application form.

One of the lessons learned that I'll share with you that I actually heard recently from one of you all is that, when you're teaching your staff about this, just because they change the extension from .doc to PDF does not mean it's been converted to PDF. You have to go through a formal process to convert a word document to a PDF document, so keep that in mind. And then we'll give you some other helpful hints as well along the way, but one of them that we'll reinforce here is that, in your text attachments, do not include any headers or footers. Don't put page numbers. You don't need to put the PI name on each page as you do currently in the 398 process. Our system is going to do that for you, when we put the application together after it's been received.

We've developed two application guides specific to the SF424 (R&R). One of them is for general instructions, and then we have developed a separate guide for just the SBIR and STTR programs. These include instructions that are imbedded in the actual form. When I show you the form, there's a place where you can turn on the form-sensitive help, it's hover-text that pops up when you hover over a particular data item. Well, that's real cute at first, but it can get annoying really quick, and so what we've done for you is, all of those instructions that are actually embedded in the forms we've included in that Application Guide.

We've also included some agency-specific instructions. We found that there were some data elements that needed a little bit more clarification for our needs, and so those agency-specific instructions are denoted by being indented a bit, and then we have that HHS logo next to those, so you can realize that that's something in addition to the form-embedded instruction that is specific just to NIH submissions.

There are, right now, two versions of the Guide in use. Version 1 is still up there, and it will be until the end of this calendar year, because we still have some announcements out there that are still using Version 1 of the forms. For any of you that have lived through this with us in the last year, you know that last spring we went through a major form conversion when Grants.gov upgraded the forms from one schema to another, and we labeled those "Version 1 and 2." And so we went through what we like to call a reposting party where we had to repost every announcement that was out there to show the Version 2 forms. But some of them, if they only had a short life span and were due to expire by the end of this calendar year, we left Version 1 up. And so that's why there's still a Version 1 Application Guide. We're going to be pulling that down after all of those announcements have closed.

Version 2 is up there, and you've probably heard us talk a little bit about the fact that there's now a Version 2A form. I want to assure you right now, we will not be reposting everything that's out there. The only difference between 2 and 2A -- I'll get into a little bit more detail -- but the only difference is we are now starting to use the new Senior/Key Person expanded component. That's the only difference in the 2A packages is that we took out the old Senior/Key Person component, plugged in the new, expanded component, and have started using those packages since the week of November 13th. So we will not be going back and reposting, it's just, from November 13th forward, we've been using the 2A packages in all of our funding opportunities.

As Megan mentioned, when you actually get to the download page, there will be a link that takes you to our website, to where we have these Application Guides housed.

Just a little bit of a word about our Application Guide -- we've heard some comments about it. It is, indeed, a very dense document. I'm not apologizing for that. You need to consider this more than just application instructions. It is a full resource. An awful lot of the information at the very beginning is about how to submit the application, so everything you need to know is in one place in this Application Guide. But for the basic structure of the Application Guide, we kept it as close to the 398 instructions as possible. Part 1 is for the instructions -- are indeed the instructions for preparing and submitting the application. Part 2 are your supplemental instructions, if you are submitting an application that involves human subject research. So if your application does not involve human subject research you only have to read the first 118 pages of the Application Guide in Part I , not Part 2 as well. And Part 3 continues to be your reference section, where policies, assurances, and definitions are maintained.

Okay, here's where you're going to want to have your other handout handy, so that we -- as we walk through each of the various components, you can look at that as I talk through the text slides, because that's going to be a lot easier for you to see than the visual aid that's actually in the slide set itself. We're using that, more or less, just as a transition slide.

So the very first thing that you see when you download the package is something we call the application package header. This is attached to every posted application package, and the data here is indeed pre-filled, as Megan said, pre-filled from that Funding Opportunity Announcement. It also indicates which are required or mandatory components and which are optional in each of the announcements. You will see a section there that says "mandatory" right in the center, and then below that are your optional forms.

This includes some basic instructions that Megan will actually go through because there are -- this is where you come back to when you get it all done and are ready to submit, and Megan's going to take you through that part of it in a little while. It also includes some application submission and verification screens that you'll see after we've walked through all of this. So this is what it looks like.

A couple of helpful hints on this. First one is the CFDA number. You'll see, in this particular example, it's blank. That's okay. You want it to be blank. Don't try to enter anything in there. The Grants.gov system was developed under the premise that there was a single CFDA per funding opportunity, and for any of you familiar with NIH business, you know that is not the case at all. We could have -- probably in the R01, we probably have forty, fifty CFDA numbers, for instance, and that's common across NIH, to have multiple CFDA numbers. And so, in those cases where multiple CFDA numbers are part of an application -- of a particular Funding Opportunity Announcement, this will be blank. Don't worry about it. Don't try to fill it in. I'll tell you this again when we get to the cover component in a few minutes. Our system will be assigning the correct CFDA number once we've assigned it to the appropriate institute here at the NIH, so you don't need to worry about it.

Here's where you're going to see -- in the competition ID -- that's where you'll see a reference to either 2 or 2A for the forms. If that's blank, it's still Version 1. We didn't realize when we started this that there would be a Version 2, so we weren't putting a label into our Version 1 a year ago when we started through this. And then, here, as I mentioned, is where you can see the mandatory forms, and then right below them -- can't see it on this particular screen, but you can see on your handout -- the optional forms.

All of this is pre-filled. You don't need to try to fill in any of this information whatsoever. As I mentioned, this button up here is what you can click on for field-specific help. Once you turn that on and then you hover your cursor over any data field, a little bubble will pop up that tells you some additional instructions for that particular data field. Helpful at first, but I can tell you, it quickly moves over into another category.

And then some form functionality for you, that I will highlight here. Any field in the forms themselves that are considered mandatory fields, required fields, there's two ways those are noted. They show up as yellow in the form field itself, and then there's a little asterisk right next to the form field title. So any time you see an asterisk and a yellow field, you know that is a required field. It will not let you submit if there is data missing out of any of those required fields.

Okay, flipping now to the next component, which we have called the cover component. In the R&R, it's just called the SF424 (R&R) -- well, we use that term to talk about the whole data set, so, for our purposes today, we're going to call this particular component a "cover component."

Okay, for those of you familiar with the 398, there's a lot of the same similarities here. It provides some general information about the applicant organization, as well as the contact information for the PDPI -- new term, combined term now -- as well as the Authorized Organizational Representative, so basic information. But then it also gives us some application-specific information like the type of application and the title, things like that, so it's a catch all, that -- lots of general information about both the applicant organization as well as this particular application.

But there are some nuances here, things that kind of trip you up, particularly if you're familiar with NIH business, and so that's what we're going to try to do right now is highlight some of the things that may take a little bit of a learning curve to get them ingrained in your new memory here. And the first one is the very first item: Type of Submission. The first value that you see there at the top left-hand corner is Pre-application. For the most part, NIH will not be using this. Only in a few very specific Funding Opportunity Announcements will you see Pre-Application as an option, so in general this is not something you will be normally checking. But one thing that you may actually be checking, at least initially, quite a lot would be the "Changed/ Corrected Application." And this is what you need to indicate when you are correcting an application that failed the system validations that we've been telling you about, and that Megan's going to go into a little bit more in the last section.

This is not what you check if you are checking -- if you are sending in what we used to call an amended application. That's now a Resubmission, and we're going to talk about that in just a few minutes. So "Changed/Corrected" is only if you have to send it in again because it didn't pass validations the first time, or you needed to rejected it because there was something that happened to it in the first transmission. That's when you now use "Changed/Corrected."

The next item that takes up the whole section right underneath there, is item number 5, "Applicant Information." Keep in mind, this is for the applicant organization, not the PDPI. We'll get to that down below in item fifteen. Item 5 is for the institution. And in particular, oone of the most critical data elements for NIH, in this section, is your organizational DUNS number. This must match the organizational DUNS number that you have registered in your eRA Commons profile for your institution. That is one of our validations that we do check on our side when we receive every application, so you need to double-check to make sure that the DUNS number that you've registered in the Commons is indeed the same one you're using on applications.

Keep in mind, it must be an organizational DUNS number. Many of you have Principal Investigators or are Principal Investigators that are also NIH peer reviewers, so you might have a personal DUNS number now in order to receive your compensation for being a peer reviewer. That is not to be used for an application submission. The DUNS number here is the DUNS number for the applicant organization, not an individual. Many of your organizations have multiple DUNS numbers. You as an organization, as part of your decision-making on how you're going to deal with this new business process, you need to decide which one you're going to use for application submission, so if you have multiple, pick one.

The next item that -- still -- I can't remember the new terminology yet either, I have it posted up on my wall. Item number 8 is the Type of Application, and this is where we are indeed getting into some new terminology. "New" is the same. That one's an easy one. "Resubmission," though, that's the equivalent of what we used to call a revision or an amended application. Those are now "Resubmissions." A "Renewal" is equivalent to our "competing continuation," or in NIH-speak, a Type 2. So that's now a Renewal. "Continuation," that's essentially equivalent to our Progress Report, and NIH is not planning at this time to have those come in through a Grants.gov submission, so "Continuation" would not be a data field that you would be checking. And then the last one is "Revision," and this is what we will be using if you are ever going to submit a competing supplement to an existing grant, then that will come in as a Revision. Administrative revisions, though, again -- or administrative supplements, again, we will not have those come in through Grants.gov. This would only be for any competing supplement where you're increasing the scope and it has to go through the peer review process, then you're going to check the Revision item there.

We have provided this terminology crosswalk in the instructions. I also -- if you have a chance when you get back, just print this slide off -- this is what I have right next to my computer. After a year and a half of working with this, I still have to look up Resubmission for some reason; I just can't get Resubmission and Renewal in my head yet.

Okay, the next item that tends to cause a little bit of heartburn I've already touched on in the header page, but let's reinforce it here. Item 10 is where the CFDA number is. This is another example of where data is pre-populated, so this would be pulled from the header, from the Funding Opportunity Announcement. So again, if it's blank here in the cover component, don't worry about it. Don't try to fill it in. If it's the wrong one showing, don't try to edit it. Just don't worry about the CFDA number. We'll take care of that at our end if it still needs to be assigned once we get it in. That's your take-home message on CFDA numbers.

Oh, one more thing before we move on to the next component. I don't have a slide on it, but I do want to talk about it since Megan mentioned -- I'll be interjecting some Multiple-PI helpful hints as well. On item 15 of the cover component, you'll see, is PD/PI. If you are indeed submitting an application that involves multiple Principal Investigators, the contact PI is the one that needs to be listed here in the cover component. The rest of them, we'll talk about when we get to the Senior/Key Person component, but for Multiple-PIs, it's the contact PI that's included here in item number 15.

Okay. Next component is the Project Performance Site. Very similar to our form page 2 in the 398, the Performance Site Section. In the (R&R), though, it gives you structured data fields where you can enter individual data for up to eight locations, and then greater than eight locations there's an attachment button there. This is probably the first of many attachments you'll see as we walk though this, where you can just put the rest of the information in one single text attachment, what we call the "blob," and attach it here. However, we have provided you a tool for this. We've actually created this component in Word and it's on the forms website, so that if you do need to attach one of the performance sites attachments here, you can go to our website and pull that down and all the data fields that you need to have entered are in that word document. Then you'll convert that to PDF before you attach it, but we have provided you with that tool.

The next component is the "Other Project Information" component. This one is kind of a smorgasbord. There's a lot of information provided in here. Here's where you give us information on the use of animal and human -- vertebrate animals and human subjects. There's questions here you have to answer on environmental impact and foreign involvement. And then, at the bottom of this section is where you start really seeing a lot of the attachments. There's a separate attachment here for the project summary or abstract description, what we're used to calling an abstract description. Then there's an attachment here for project narrative, and here's where NIH is being a little bit unique in the use of a particular upload. You'll see a little bit later where we've developed a separate component for our Research Plan, and so here, in this project narrative, we have a special instruction that asks you to include that public health relevance statement that we added as a requirement to the 398 a couple of years ago. That's where you need to just tell us, in plain language, the public health relevance of this particular project. That's what gets uploaded into that spot.

The next -- there's an attachment here for bibliography and references. This is what used to be part of the Research Plan, section G, literature cited. That's now here on this component. And then the last two are Facilities and Other Resources, and Equipment Resources. Again, separate attachments for each of those. That's -- for many of you familiar with the 398, we had a separate resource format page. You can't use that anymore, so don't try to just take that from a 398, because you need to -- you could take the text out of it, but save it in its own new Word document, because it's two separate sections, now, that need to come in. One just talks about facility and other resources, and then the equipment is separate. So don't try to use what you used in a 398. Convert those to two separate documents that you can convert to PDF and change as needed.

The next component we're going to talk about is the Senior/Key Person profile. And this is where the -- this is the only place where the difference is between versions 2 and 2A. So, in version 1 and version 2, we still have the old Senior/Key Person profile, which captures personal profile data for the PD/PI plus seven others, so it maxed out at eight -- structured data. After eight, you had to then just put it all together in one blob and attach it. Again, we provided you with -- on our website -- a Word format page that gives you the same structured fields to make sure you're including that for any of those that need to come in as part of the blob. And so that information is on the web page.

But what we did in -- for 2A -- and I'll talk about what's circled there in just a minute, 2A is the new expanded component. What the expanded component allows is up to 40 Senior/Key Persons to be entered as structured data before you get to the blob options of anything over 40. So that's the difference between the two. Anything that's still in version 1 and 2, you max out at eight, and then you have to put it all together in a PDF after that. For 2A, which is all the opportunities that we've posted since the middle of November, now you have the opportunity to give us up to 40 individuals as structured data, and then, after that, you can put it in as the blob. I love that technical term.

So this is how this Senior/Key Person expanded component actually works. There's a second page to it, and what happens is, after you filled in the first eight, then this button shows up and becomes active. And it's hard -- a little hard to read on the screen, but it says, "Select to extract the R&R additional Senior/Key Person form." Very lengthy, but essentially what it does is, when you click on it, it gives you another Senior/Key Person component that you can fill in. And you can extract up to four of those, so you can go ahead and extract all four if you know you're going to have 40more -- or up to 40 people, you can go ahead and pull out all 40 of them and fill them in locally. So you can extract that for each one. And then after each is filled in, then that's where you attach them, then. You come back to this form, this second page of this form, and you attach them there. Only after you've attached all four of these will these blob buttons become available, and that's what shows up where you can just do anything over 40 as one combined upload.

So that's how Senior/Key Person expanded works. If any of you are familiar with the Sub-award, the form in -- what they call the form-in-form attachment, it's the same kind of concept. You hit this button and it just gives you another blank component for Senior/Key Persons.

A couple of other things about the Senior/Key Person component in general. You put in the structured data for each individual, and then there's a place for the biosketch. The biosketch instructions are the same as they were in the 398. You can still use the same biosketch formats that you've been using, however you do need to remember to convert those to PDF before you attach them. The other attachment there for each individual is for other support, "Current and Pending Support," what we've known as "Other Support." You do not need to use that at the time of application submission unless the FOA specifically says that. We will keep our Just-in-Time process and gather that information from you later in the application process, for those likely to be funded, so we haven't changed that business process at all.

I think, probably, the biggest thing, though, you need to highlight here, and when you are doing outreach and education and training at your institution, this is where you need to highlight it, use dancing ants, whatever you need to do to draw attention to this particular data field in the Senior/Key Person component, and that is the Credential field. This is where you have to enter the PD/PI's Commons User ID. It will not pass validations without this. In fact, you won't even get to any of the other errors that you're going to hear about if this -- this is one of the real showstoppers for us. It won't even get in the front door if this field is not accurate or if it's empty.

In those cases where you are submitting applications that involve Multiple-Principal Investigators, you're going to want to make sure you include this for everyone that has a project role of PD/PI. This component allows more than one person to hold that role, the PD/PI role, so you can, for -- if you are submitting, and only if you are submitting an application with Multiple-PIs, you can assign more than one person the PD/PI role, but you must, then, also include the Commons credential, the Commons User ID for every single person that is assigned that role.

Okay. So I think I've covered -- oh, one of the -- one of the reminders for the biosketch, if you've been with NIH business for a while, you know that up until about a year ago, we had subsection limits in the biosketch. It's a four-page limit, but you had two pages for only certain parts of it. That's been eliminated. That was eliminated for all biosketches last spring. And so now it's just a four-page limit, period, for the entire biosketch.

We talked about that. Okay.

On to the next component which is the budget component, the Detailed Budget component. We'll talk in a minute about Modular Budget because we will still keep that business practice as well. But this is the Detailed Budget component for anybody using the R&R data set. It's a little bit different, so we are going to take you through it. The first section is personnel, and it's actually subdivided into two sections. The first section is Senior/Key Persons, and again, it allows upto eight to be individually entered with structured data, and then there's an attachment where you can include more than eight. And then the first line item there for the PI, that automatically comes over from your cover component, so that's another example of where some data is pre-populated from earlier in the application. So you must enter something in that first row, even if it's zero.

And then down -- the second part of personnel is classified as "Other Personnel," and this is where you just have the numbers only for postdocs -- graduate students and undergrads. You don't actually list them as names unless they've been already classified as a Senior/Key person. We, however, continue to have some business processes that we must monitor. We have a limitation on graduate student compensation, for instance. We have a very rigorous postdoc fellowship program, so we always are checking for overlap, and so we do have some agency-specific instructions where we require some additional detail in the budget justification for these category of personnel also.

Probably one of the biggest culture changes for all of us is the change in the metric for how we now deal with percent effort being devoted to the grant. It's no longer a percentage. It's now provided to us in person-months. So you must enter either calendar, academic, and/or summer months for all Senior/Key Persons, as well as the other personnel as well, only those are combined totals. Because this was such a significant business process change for us, we did go ahead and also change it in the 398 and in the

2590, our Progress Report, last spring, so that all of our applicant community would be dealing with a consistent business practice regardless of what application was being submitted. But that -- I can tell you that is probably one of the most significant things that NIH staff has been wrestling with as well, and so we've provided you with some tools to help you with this. There are some frequently asked questions, and then a calculator which will help you convert percent efforts into person-months depending on whether you go by an academic year that's nine months or ten months, or a calendar year. This has become probably one of the most helpful, useful tools we've heard about that we've provided for you as part of this transition.

The next section of the budget page is equipment. Again, it allows itemization of up to ten items, and then anything greater than ten you have to lump it together. There's one line there to put anything greater than that, and a place where you can attach the details in an attachment.

Travel. You'll notice that the R&R does indeed separate out domestic and foreign travel. At this point in time, NIH doesn't plan to change our award at all. We will continue to award that as a single budget category. We will not be changing any of our business practice with respect to that.

Participant/trainee support cost. In most cases, you will not need to use this for NIH applications unless there are specific instructions in the Application Guide. Tuition remission. We've got a special instruction in the next section for you to include that information there, and we found, as we looked at this, that this section -- we thought we might be able to use it for when we get to our training grants, but it actually doesn't give us the kind of data we really need, so we're probably going to be -- we are developing a separate budget component to help capture that, so we won't even use this Detailed Budget component there.

And then the last couple of sections of the budget. "Other direct cost." Here, again, a little bit different. We've itemized out supplies, which we're used to seeing, but there's also separate sections for publications, consultants, ADP computer services, consortium costs -- that's still an important one -- equipment, etc. You can see here, we've also included some agency-specific instructions. This is where -- there's blank lines in section F as well, and it's the blank lines where, if you have an application involving patient care costs, for instance, we've got special instructions in there for you to use those blank lines. And this is where we want to see, also, the separate line item for tuition remission.

All the totals the form will calculate automatically, you won't have to do that. There is a separate section for Indirect Cost. You can include, or you have to include, details there, as well as the dollar figures. There's some text-entry sections for the Indirect Cost also. For SBIRs and STTRs, there is a separate budget line item for fee, and then finally, at the very bottom, is the Budget Justification. Again, this is a text attachment. You can use whatever word processing package, but you need to convert it to PDF before you can do the attachment.

One of the things that hangs people up a little bit on the budget. At the very top of the last page of the budget, if you look on your sample here, you can barely see it, but just after where it says “budget period one” there’s a grayed-out button that says “next period.” That will show up only after you have entered in all the required fields in budget period 1. And that includes the budget justification, unfortunately, but that is a form function that we’ve reported as a desired change. We don’t know if we’ll be able to get that fixed or not. The budget justification is a single justification for all five years, but you have to attach it here before that next period button even shows up for you to go to year 2.

So, you actually now have to complete a detailed budget for year 1, year 2, year 3, year 4 and year 5. There is no longer a summary budget as we have in the 398. It is a detailed budget for every year of budget that you are requesting. The system, however, will calculate the cumulative budget for you. You don’t need -- that is not something that you have to calculate.

The next component is the Sub-award budget attachment, and it’s the same kind of concept that we just went through with the Senior/Key Person. If you have a grant, if you’re putting together an application that involves a consortium grantee, then number one, you got to make sure they have PureEdge, and then you come to this Sub-award budget component, and you click on this big button in the middle again, and what it does is extract a budget component like what we just walked through. Just gives you a separate budget component. You ship that off to the consortium grantee. They fill it out. They send it back to you. They have to have PureEdge, so they already load it, so they can fill it out. They send it back to you, and then you can attach it here. So it’s that same kind of form-in-form concept. This is one of the few places where the attachment is actually a PureEdge form, and not a PDF, so this is one of the few places where that’s okay.

As you see, this allows up to ten. I know, your question is, what happens if you’ve got something that has more than ten? For right now, this is the maximum that the R&R form data set can accommodate, so if you do have more than ten, we’ve included an instruction that you just have to combine the rest as part of your budget justification. Always remember, though, regardless of how many subcontracts or consortiums you have, you’re going to make sure you -- in the prime budget, the detailed budget for your own applicant organization, F5 has to have the total. F5 is where your consortium sub-award line item is, and that’s where the total has to go, regardless of how many attachments you’ve provided here.

Let’s see… Oh, this Sub-award budget attachment is only necessary if the prime applicant is creating a detailed budget. If the prime applicant is going to use a modular budget, you will never need to use, as part of the application that comes in to us, this Sub-award attachment. It might be in the package if both budgets are in the package, but if you are -- if you are completing a modular budget, the Sub-awarders or consortium grantee does not need to send in a detailed budget to us. We’ll talk -- that -- we have a separate component for dealing with modular.

Okay, I think I've gone through all of those, so now we're on to the last component that is part of the federal-wide data set, or will be. This one will eventually become part of the federal-wide data set, and this is the form that is just specific to the SBIR and STTR programs. One of the nice features about the R&R: by dividing all of this up into various components, an agency can pick and choose which components you see in the application package, so you won't ever see this component unless you are actually responding to a particular funding opportunity that is specific to the SBIR and STTR community.

This component includes some eligibility questions that are answered by both, as well as, then, separate sections for just SBIR and a section for just STTR questions. And again, you've got a PDF attachment here, which is where the commercialization plan is provided.

So those are all the ones in the common data set, and now I'm going to take you through those that are agency-specific, which we've titled the PHS 398. First one's a real easy upload. It's just the cover letter. It is a single text attachment. It's the same instructions, the same information that you're used to providing in a cover letter now, in the 398, can be provided in the cover letter here. While we receive it electronically and it is stored in our electronic grant folder, it is not part of the main application image which you will have access to. It's separate, and is only seen by appropriate NIH staff, not by any peer reviewer, so we assure you that that information that comes in is separated off and stored separately and only visible to those that really have a need to see it.

It is required, whenever you are submitting a Changed/Corrected application after the submission date. So, if you submitted an application on the very last day, and you found the next day after you saw it that you needed to do a Changed/Corrected, you are now required to put a cover letter there. If you already had a cover letter, and you're revising it, please repeat all the text that was in that cover letter. That first submission is not retained at all, so we will only see whatever cover letter is submitted in the application that comes all the way through the process.

The next component is one we titled the "Cover Page supplement," and what this does is supplement some of the other data that is primarily coming from the R&R cover component. For the PI, for instance, we also have the new investigator code, that continues to be a data requirement for NIH, and becoming more and more important as we target more and more activities and programs for new investigators. Believe it or not, there wasn't a single place in the R&R where the degrees came in as a structured data field, and so we've added those data fields here.

If you think -- if you look on the actual -- the actual sample that you have there, you're going to see at the very top, you've got some PD/PI information that comes in. That -- it looks blank in the sample here, but that gets pre-populated. That's only brought over for your reference. You are not having to do any duplicate data entry. We bring that over from what you've entered already. It's just brought over there for reference, so that you make -- you're clear that the new investigator and degrees information is in response to this particular program PD/PI.

The other data fields here continue to be some of the information specific to NIH, which is our clinical trials codes, both the generic clinical trials code and the NIH-defined Phase III clinical trial code.

The next section, again, if you look back on the cover component where the applicant contact information was, like, the business official, it was incomplete. It's the only place in the R&R where we didn't get a full address, and so we still need that information because right now that's what we use to mail the award for those awards that we still have to hard-copy mail. And we also sometimes use that information to contact the individual. So for now, we're continuing to ask for that additional contact information, but again, what you put in in the cover component automatically gets pre-populated in the top half of that section. You are not having to retype that information. It comes over from what you already entered, and then you just have to enter the title, the street, city, state, etc., that additional address information. And then, finally, it includes the data fields for human embryonic stem cells information.

The next component is the Modular Budget Component. We have not done away with that business practice, and so we have accommodated that by developing a separate budget module. You are going to find, in many packages such as the R01, you will see both the detailed budget and the modular budget as down in the optional forms. You need to pick one. The system will not allow you to submit both. You have to pick one or the other based on the modular rules. Nothing has changed there. And so we've accommodated the same kind of data needs that we had in the 398 in this component as well. You do need to fill out the individual information for each of the budget years. 1, 2, 3, 4 or 5, but then the cumulative budget is system-generated, just as it is in the detailed budget. Then there are separate PDF text attachments for the budget justification for personnel, consortium and other.

Okay, the Research Plan. This is the one where a lot of people start getting a little anxious when they see the number of attachments, but we want to remind you that you can still create your Research Plan as a single document, so use whatever word processing package you use, and just create it as a single document, and you only have to break it up into the various attachments at the very end, before you attach it into the form. Why are we doing that? Well, we're trying to take as much advantage of system validations as we can, to improve and to shorten this process as much as possible. And so, by doing that, we can do validations automatically, for instance, on page number limits for the sections that have page numbers. If you've had a chance to look at one of our images that's come in, they're beautiful and they're bookmarked. The bookmarking is vital to the separate -- separate attachments are vital to the accurate bookmarking, and so those are some key features behind why we are asking for these separate attachments here. It's the same formatting requirements with respect to fonts, margins, page limits, etc. Nothing's changed there at all.

The other take-home message on that one, I guess we'll talk about that in a few minutes. So I do have some helpful hints.

And then the last attachment in this Research Plan component is appendix material. It allows up to ten separate attachments. You don't need to use all ten, no. It just accommodates up to ten should you have that. And again, the appendix material will come in, and it's stored in our electronic grant folder, but it has its own little place in that folder. It's not part of the rest of the grant application image. It is stored separately. And it's accessible to appropriate NIH staff and peer reviewers. Appendix material goes to the peer reviewers as well.

One of the things I want to remind you -- if you haven't had a chance, please take a look at the Guide Notice that we just published a few weeks ago concerning the changes in appendix requirements. Those changes have been incorporated in the instructions that are now -- the application instructions that are now on the web as well, and those changes are effective with all submissions that begin in calendar year 2001, January 3 and beyond. So please, if you haven't taken a look at this notice, make sure you do before you're starting to put together any application that's coming in in the new year.

Again, reinforcing the helpful hint here, create it as a single document, then separate it at the very end. Don't include headers or footers. We're going to do that for you. But as you're creating it as a single document, it's okay to put a section header, so you can do specific aims and then your text, and then a section heading for background, and then the text, so go ahead and do that. That's fine, but you don't need to put a header on every -- right now on the 398 you put the PI name as a header on every page. You don't need to do that. Don't do page numbers as footers either. We'll take care of all of that. And avoid the two-column text that you may have gotten used to using in a 398 or sometimes some of our reviewers have indicated since we're moving more and more towards reviewing these online as well through an electronic system. The two-column format makes it a little bit more challenging to read.

And the last page, the last component that we're going to walk you through, is titled "The PHS 398 Checklist." Again, this captures some of that additional data that we had back on the checklist in the 398. You can indicate whether this submission also includes a change of PI, whether this submission also includes a change of grantee institution. The inventions and patents information is still there. Program income information is still there. And finally, if you find there's any of the policies or assurances or certifications that you're not able to comply with, there's a spot there for you to provide us that information as well.

So that takes you step-by-step through each of the form components. It's a lot of information to absorb, there's no doubt about it, and there is a learning curve involved in it. So we're not, you know, we're not expecting you to be experts overnight, but with time it really does become easier, and you do -- as with anything, you start to memorize the nuances to this as well. And so now Megan's going to take over and take you through the rest of the process, and then we'll have a chance for some lessons learned, I guess, after that. Thank you.

[applause]

Megan Columbus:
Okay, so, the title of this is, "Application Complete… Next Steps." Is your application really complete? Well, it's not complete until you've submitted it. So you've finished putting it together. Some things and helpful tips here: Make sure that you save the completed application to your hard drive before you submit it so that you have a copy locally. You need to be sure that all the mandatory documents are completed and have been moved over to the right-hand column of that page, and you need to make sure that you look at the agency-specific instructions for which optional documents are required. And you'll see, on the top, the "Check Application for Errors" button. It's a very good idea to check the application for errors to ensure that your application can be submitted to Grants.gov successfully.

Now one of the challenges for NIH in this whole process is, this is a form that's used by many federal agencies for their research programs, and this "Check Package for Errors" button is only going to give you the errors that are common to all of those agencies, which means that NIH-specific business rules like enforcing page-limits in a Research Plan, or making sure there is a human subjects justification if you've checked "human subjects," or making sure there's a leadership plan if you're using multiple PIs, none of that is anything that can be done up front from this software. That can't be done until it hits NIH. So when you check the application for errors, know that it's checking to make sure that you've filled out the form in accordance with the instructions for all agencies, not for NIH in particular.

Once you've checked the package for errors, and right now it gives you one error at a time. NIH is on a group that's providing feedback to Grants.gov, and one of the things that we hope they will change is the ability to see all errors in this application, with a single click.

But once you've checked your package for errors, in the upper left-hand corner, you'll see there's a submit button. So your Authorized Organizational Representative is the one that will click submit. Automatically, it'll take you online to Grants.gov and will ask the AOR to log in. So the AOR will log in using their username and password. They'll have the opportunity to sign and submit the application, they need a little bit of luck. What they're going to get -- what the AOR is going to receive back is a Grants.gov tracking number and the date and time of receipt. Applications are due to NIH at 5 p.m. your local time. Okay, that's the timestamp that needs to be given by Grants.gov for the submission, alright?

Save this Grants.gov tracking number. If you have any kind of problems and you need to follow up with the help desk, that's the first thing they'll ask you for is the Grants.gov tracking number so you can follow your application.

So, you've submitted your application to Grants.gov, what comes next? Know that Grants.gov response time, in the low-volume application time, can be very quick. It can be minutes; it can be hours. Their service standard, however, is two days. And so it could take your application two days for Grants.gov to process your application and make it available for NIH to retrieve from Grants.gov. When NIH -- once NIH retrieves your application -- we generally process it within minutes, hours, but it can be up to one weekday, okay? So recognize that there could be a lapse from the time that you submit to Grants.gov and the time that you can see the results of your submission in the eRA Commons.

And I'll talk about this a little bit later, but once your application gets to the Commons, and if you've followed all the application instructions, you'll get your application image. So you'll be able to look at your application. You'll be able to check it to make sure that it is true to what you submitted. And that's where you'll be able to see the table of contents and the headers and footers and you'll be able to make sure that the attachments that you attached aren't your son's homework, or whatever it is, but that would be an important thing for you to check.

So Grants.gov, when they do their validations, when they check your application when it gets to them, they check at a very high level. They make sure that you've filled out all the required fields. They ensure that you have moved them all over to that completed documents box. You will know that in advance, if you've done all those things, because you've already hit that button on your application, "Check Application for Errors." And that's what that button will tell you. It'll give you those types of errors. The only two other things that Grants.gov is checking for is making sure that the DUNS number is registered appropriately to the organization in Grants.gov, and it checks the email addresses and scans for viruses and that kind of thing.

So what Grants.gov does whenyou've submitted your application. It'll send back an email to the Authorized Organizational Representative saying that it's received the application, that it's validated the application, that it's made it ready for agency retrieval, and that the agency has picked up the application. Okay? So you'll be able to follow out the email trail. Grants.gov also has a way that you can just log in and see where your application is on the site, in case you don't get any emails. I would recommend throughout this process that you bear the burden of making sure that your application's being processed appropriately. You're not finished until you see the application in the eRA Commons as an image, okay?

So once you've gotten those messages from Grants.gov, then the eRA Commons has gone and picked up the application from Grants.gov and started processing it from the NIH side, all right. You'll be getting different emails from NIH, and NIH understands that PIs very much want to be able to track their applications, so NIH is sending an email to the PI and to the Signing Official, and I believe we send an email to the contact person on the application as well. It says that NIH is processing your application. By that it means that NIH is looking at your application to ensure that you have complied with the instructions for the page limits and for the required documents and all those things. What it's going to do, then, when you check the Commons, it's going to tell you the results of its processing. It's either going to say, "Everything's great, here's your application image, just look at it and make sure that it's okay." Or it's going to say, "You know what? We've found some things that you weren't compliant with or some things that you want to pay attention to."

Okay. There's a variety of emails that you're going to get that's going to tell you these things, and the way you can tell what happened in your application is, if you're -- right now I'm pretending to be a PI. I'm going into the Commons. This is the Commons screen. I'm clicking on the "status" in the topmost menu bar. I see, in my status, that I have an e-submission error. I'm either going to get something that says "errors," or the better path is, you're going to get a transmittal sheet right here. Either way, you click on the grant application number, which will allow you to either view the application, or to see your errors. These are example errors. These are actually errors from way early on in the process. The text has changed, and I think even some of them have changed whether they're errors or warnings, and I'll tell you the distinction for those in a minute.

But these are things that -- we need you to pay attention to, okay? If it's an error, you must address the error and submit a corrected application back through Grants.gov in order to address that error. Only error-free applications will generate an image in the Commons for you to look at. It is not submitted to NIH until it's error-free. The kinds of checking that we used to do manually after your application got to NIH -- that's when we would start checking it to make sure you're in compliance with page limits, and that you've followed all the instructions, and that you have all the required documentation, that's now all be doing -- all being done upfront by the computer system, okay? So that's important. That means that in order to fix an error, you're going back to your desktop, because you've got that application on your desktop, changing it in the application, and submitting it to grants.gov.

Warnings are alerts to an applicant. They may want to pay attention that -- they may want to look and make sure, in their Funding Opportunity Announcement, that they haven't exceeded page-limits, or whatever that warning might be. Warnings do not have to be addressed. Applications with warnings very frequently are fine, and they can go on and be submitted to Receipt & Referral.

So if the PI corrects any warnings or errors, they need to be contacting their central grants office. It's the AOR that's submitting that corrected application back to Grants.gov. Note that warnings -- if you only get warnings, you will still get an application image. You will have two days to view that application image before it moves on for processing and for assignment to a study section. So that two days is a holding pattern, because we recognize that you haven't had an opportunity to look at your application in its entirety. And, in the same way that I wouldn't expect any PI to want to put an application into a FedEx box without having carefully looked through it, this is the same thing. This is the opportunity to actually look through the grant application. If the grant application only has warnings, we'll get this image, and two weekdays later it'll move on to Receipt &

Referral for processing. If the PI wants, at that point, to change the application, then they have to contact the Authorized Organizational Representative so that the Authorized Organizational Representative can reject that application.

If I am the AOR, or the Signing Official, in order to check the status in the Commons -- now I'm in the Commons. I'm logged in with a different role, so now I'm an administrator. I will click on the "e-Applications" button over here, and then I'm going to click on "Show Submission Errors." I'm going to do that because many organizations submit a whole lot of applications to NIH, and you certainly don't want the initial search page to be cluttered with hundreds of applications, so what this does is it lets them deliberately go in and look for that.

They can -- in this case you'll see there's a transmittal sheet, which means that the application has processed successfully. They can go click on the application ID number to view the application. If, when viewing the application, they find that they need to reject it because something got garbled in transmission or something didn't come through as expected, they have the ability, on this screen, to reject the e-Application. If the AOR rejects the application, that triggers an email, that goes to the PI as well, to let them know that their application was rejected.

When they click -- sorry -- when they click on the application ID number, it brings them directly to this screen where you click on "E-Application" to be able to view the application image. So this is what the application looks like in the system. Notice the bookmarking up and down the left-hand side. Make sure, especially, that you check your attachments. Make sure you check your graphics to make sure that they came out as you expected. We're showing you basically what's in your PDF when you submitted it to us, but we need to make sure that it's right. What you see in this application is what a reviewer is going to see.

If your application moves on to review, and then you notice that there is a problem, you may be able to make a correction with your Scientific Review Administrator. You would have to talk to them about that, but the Scientific Review Administrator will add your correction to the application that came in. They are not actually substituting pages for you, so know that the reviewers are going to be able to see this, and it's important to review it.

Okay, again, the Authorized Organizational Representative has a two weekday viewing window to reject any application that has system formatting errors. If the application is not rejected within those two weekdays, it will automatically proceed to Receipt & Referral.

So now your application is complete. There is a slide that I realized that we did not include here that I will add to the presentation and post onto the website so that you will have it, and that's "On-Time Submission." So it's hard -- you see that there are these viewing windows and there's, you know, you have to correct errors. What is on-time submission? On-time submission to NIH is, you've submitted your application to

Grants.gov by 5 p.m. on the receipt date, your local time. Okay? Because this is a new process, for the initial transition period, NIH has given a one-week period for you to address any errors that arise in your application. So if you got your initial application to Grants.gov by 5 p.m. on the receipt date, you then have that one-week period after the receipt date to address, and make any corrections that address the errors that you received. After that receipt date, however, you will need to include in your cover letter, in addition to whatever you had in the cover letter, the reason for your corrected application. You would have to say specifically "I'm addressing this error." So that's what's going to constitute an on-time submission. If, at the end of that week, you get your final application image, you then have two [week]days to view that image before it automatically moves forward for referral to a study section. Okay?

So now you're happy. Your application's complete. You got through the system. Where are your resources? It'll be really important for you to know. I'm sure you'll have questions. We'll answer as many questions as we can here today, but we have a ton of information out there that you can use. Most of it's centered on the Electronic Submission website. I would suggest bookmarking this page. You'll find all kinds of things. You'll find sample documents so you'll know how the application you're filling in assembles into the final application image. You'll find sample application packages and additional formatting pages. You'll find lots of training tools, communications tools, outreach tools. If you need brochures, if you need fliers for your institution, if you need presentations -- you want to borrow our presentations, we'll make them available to you. There's automated training demos for the eRA Commons. There's video training that's done in a more formalized way than this one that might work for later viewing better than this for you if you'd like. There's "Learning the Electronic Submission Process" that are videos; there's hands-on learning to walk you through the process if you need more than what we've done here today to play with the application some. There's presentations, there's sample application packages. Remember though, there's sample application packages out there. Be careful that you don't use any sample application packages for actual submissions. It doesn't work that way. You need to go back to the Funding Opportunity Announcement.

There's demos on registration. There's application guides. There's all kinds of FAQs and advice about avoiding common errors. If there's something out there that you need that we don't have, you know, send us an email, let us know -- we're pretty responsive to those kinds of things.

In terms of getting help beyond the online resources, knowing who to call is important. We talked about this being two separate systems run by two separate organizations. We'd love to be one federal government for you, but we can't expect Grants.gov, who is servicing 26 agencies, to know the details of NIH business rules. It just doesn't work that way. What Grants.gov will be able to help you with is the actual submission process. So if you're having problems with the PureEdge forms, or for some reason you're hitting "Submit" and it's not transmitting the way you expect it to, those kinds of things, or registering for Grants.gov, that's what Grants.gov can help you with, because they own that upfront piece of this whole thing, all right?

eRA Commons is the NIH folks, so we own everything after that fact, so if you have submitted your application to Grants.gov, but you're not seeing anything in the Commons, let us know. We need to help you find that. If you don't understand what your errors or warnings are, and you don't know how to fix them, give us a call.

The best way to do -- to get support from the eRA Commons, and the most efficient way to get support, is actually the web support. This is where you can self-identify who you are and what your problem is. It'll automatically pull up your files and help the help desk get you a very specific answer faster. And it will route the question appropriately.

Now, on the one thing the technical help desk can't help you with is, you know, is what NIH expects in the application, the actual policy part of all this. And so that, just like you always have, you would go to Grants Info, our central Grants Information folks. So all of this is centralized in the Electronic Submission website.

And now I'd like to turn to Lessons Learned. One note though, actually, regarding all the resources that are on our website, a little birdie told me that, in your handouts, you seem to be missing a page or two of your forms -- all right, so -- okay, so some people seem to be. Know that all these presentation materials, and we'll update this with an On-time slide as well, are available on the eSubmission website under "Training." So know that those electronic versions are complete. Our photocopying people must have slipped something there.

And now let me pass it over to Chuck, and so we can talk a little bit about lessons learned, which will reiterate some of the main points from today, and then we'll open it up for questions and answers. I know we've been getting a steady stream of questions over email, and we look forward to being able to address as many as possible today. Thank you.

[applause]

Chuck Selden:
So, joining Megan Columbus and Marcia Hahn, we have Suzanne Fisher, who is the director of the Division of Receipt and Referral at the Center for Scientific Review, and Scarlett Gibb, the manager of the eRA Help Desk. I've just been handed a number of questions. We'll get to those in a minute. First lessons -- let's see -- first lessons learned.

Marcia Hahn:
Okay, I have the first slide. The first bullet we want to talk about is to work -- as you've already heard. We're going to reinforce it again here -- work with your Office of Sponsored Research to determine your internal process flow, and if you're in the Office of Sponsored Research, get started. We are -- NIH is only as far as we have come in the last year because we assembled a huge team of people. We did not try to do this alone, and you at your institutions cannot do this alone either.

You need to get your faculty involved, your departmental people involved, your central administration, your deans. You need buy-in from the very top to support these business process changes that you're going to need to institute within your institution. You cannot do it by yourself, and it takes time to do it, but you are going to have to make some significant changes in your business process and so you need to get started now.

How are things going to be reviewed and approved with your information now? How are you going to deal with document sharing? These are huge files when they get together. How is your IT system going to be able to do it? We don't recommend you start sending these around via email. I don't know about your email, but mine can't handle a thirty-megabyte file coming through every other day, so you've got to work with a team of individuals, including your IT folks, to find out how you're going to deal with this new business process.

The second bullet is to register now and be prepared. I think that we've reinforced that several times. You have to start early with these registration processes, but the good news is it's only one time -- one time for your institution in Grants.gov, and one time in the Commons. The ongoing maintenance, really, there, is for your PI registrations. You're going to want to keep those current, and even after you're registered, remember, as a PI, you own the data in the profile, and it is your responsibility to keep that data current. So if you registered, for instance, at the level of a fellow, and then got a new degree or something like that, you need to make sure you keep that information. Your address changes. It's your responsibility to keep that personal profile information current.

Read and follow all the instructions in the Funding Opportunity Announcement and the application package instructions. That seems like we're stating the obvious, but it needs to be stated. The Application Guides are indeed dense, but they're all resource information there, so when you have a question, the answer should be in there. And then read the funding opportunity as well, because any instructions that are specific to a particular program are going to be detailed in the actual funding opportunity.

The next slide should talk about reminders about the PDF attachments. As I walked you through that, you saw that most of the attachments are text attachments. Any text attachment must be converted to PDF, and we have some helpful hints for you. Don't use special characters in the filenames. That can cause an error when it comes through. Don't write-protect the PDF because you need to disable those security features in PDF before you do the submission. And, for those that are text attachments, don't scan that and convert it to PDF that way. Use the time to convert it from the Word or WordPerfect Document to the PDF generation software that you have. We want to be able to use computer tools like Knowledge Management to review the information in some of these, particularly the abstract, for instance, or specific aims, and we can't do that if it's a scanned-text document. So please take the time to just use a PDF generation software to convert those from whatever word-processing package you use to a PDF and not scan them.

I think one of the other things we found when we were talking recently with some other agencies, make sure, when you're checking all of your attachments to make sure they're all PDF. One of the things that hangs people up is in the Sub-award budget, the budget justification that comes in from your Sub-award, make sure that's been converted to PDF also. That evidently is one that's commonly overlooked and won't be accepted if it's submitted that way. So -- and then also, just the reminder on the PDF, you do need to use conversion software to make sure you've officially converted it to PDF and not just changed the extension from .doc to PDF. That doesn't mean it's been converted. Scarlett, you're next.

Scarlett Gibb:
Thank you. I have the third slide, two of our most popular inquiries at the help desk. The organizational DUNS in the application must match the DUNS in the eRA Commons profile. That means the DUNS that you put on the application needs to be what you have in your profile on the eRA Commons. This profile can be edited by the Signing Officials at the organization, so if it doesn't match please go ahead and change it now. It needs to be changed when you submit, and it also needs to match what you've registered with the Grants.gov CCR. So all three of these DUNS, this is where it's going to carry through and it's going to cause you issues if they don't match.

And the second one, which we have stated several times, and we need to state again, and I'm hoping someday will become so second nature that we can stop reiterating it over and over again, is make sure the Credential, e.g. Agency login field on the R&R Senior/ Key Person Profile Component contains the PI's eRA Commons user ID. This is really, really, really our most important error. It happens the most, and it's what we get the most calls on. And so just make sure you get your PI's Commons user ID and put that in there, and please don't make it up. From experience, it doesn't work -- you can't wait, you've got to have it there, so get the correct one. Get it done. Thank you. Suzanne? Megan, sorry --

Marcia Hahn:
I'm going to jump in and do another helpful hint on the DUNS number that we've just -- we know about. There's a little quirk in the form functionality. When you put the DUNS number in in the cover component, it's automatically copied over to the budget component. That's one of the fields that pre-populates for you. What we've discovered though, is if you go back and correct the DUNS number in the cover, the correction doesn't go over to the budget. So don't worry about that. We validate off of the DUNS number that's in the cover component, so that's the one you need to make sure is right. This has been reported to Grants.gov as a form fluke, and hopefully, when the new forms are moved over to Adobe, they'll be able to get that fixed at that time. So it's a quirk we know about. You don't need to report that one to us.

Megan Columbus:
When submitting a Changed/Corrected application, make sure that you check the "Changed/Corrected" box in Field 1 of "Type of Submission." That's what lets us know

that you've submitted this application before and you're just changing this, it's not a new application.

And the other thing is, allow time for corrections. So even though we talked about on-time submission being 5 p.m. local time, but then we give you a one-week correction window to get anything sorted out, that window's going to shrink, and the idea in the end, and the idea that's going to support NIH working towards shortening the application receipt-to-award time, is to make sure that all the applications come in by the receipt date without any errors. And so, submit early. I know that's easier said than done, but the reality is is submit early and good things will happen at NIH, I think.

Suzanne Fisher:
Thefirst is to use the two days to look at your grant image once you get it all corrected and in there, and to make sure that it is exactly what you intend to submit. Receipt and Referral, for years in the paper world, has been getting calls, and they all start out, "I sent my application, and then I looked at it," so we're now giving you that opportunity. But you really need to look at it. It is not our experience that the electronic transmission process has garbled it, but people can grab the wrong document, convert it to a PDF. You know, version control. You're going to have to get a really good system for that. Use those two days. You don't have to be home. You can go to the internet café wherever you are or whatever, get on the Commons, look at the image, make sure what you sent is really what you meant to send and that you have all the parts there as you intended. After the two days, at this time and probably for some time in the future, we do not have an easy way to make a correction or a substitution, so after two days and the application comes forward to us in Receipt and Referral, any corrections you make after that will be glaringly obvious to the reviewers and that may not be where you want to go.

The last one is really where Megan started. We are changing our delivery system. Okay, we are exchanging delivery trucks from a whole bunch of organizations for the Grants.gov process, and that has required certain changes in some of the logistics of how we do things, but it really doesn't change our fundamental policies or philosophy. We still get unsolicited applications. They are responding to a Parent FOA. We still have a late application policy. It applies to electronic applications. We still have a limitation on the number of amendments or renewals you submit. Basic policies are not changing. Basic philosophy of NIH in supporting biomedical and behavioral research. How you get the application to us is changing, and not to undermine the complexity of that, but just to make the point that NIH is still supporting behavioral and biomedical research, and that's really what we're all about.

Chuck Selden:
Okay, now back to the questions. Here in the auditorium we've received a number of index cards. You can get more index cards from staff or borrow them from someone sitting next to you if they have some left over. And then electronically, again, on that videocast Internet site, you can hit the "Live Event Feedback Form" or you can type in nihelectronicsubmiss@mail.nih.gov, and we have a number of those. So we'll start with the questions. When should an applicant begin the registration process?

Megan Columbus:
I'll take that. Now.

Chuck Selden:
Now. Did you hear that? That was quick. Now. If a Principal Investigator affiliates with a second organization in the Commons, does the PI have to drop the first affiliation?

Scarlett Gibb:
I'll take that one. No. The affiliations -- we do allow for multiple affiliations in the Commons, so the PI can be affiliated with more than one institution. If he has left the institution, the institution can drop the affiliation.

Suzanne Fisher:
A good example, though, that probably come up quite a bit this month is, when an investigator who's on the faculty of the university is submitting a conference grant through FASEB or Gordon Conference or something like that. If they are going to be the PI on that conference application, then the conference organization has to affiliate them, but of course they still keep their affiliation with their university or research institute.

Scarlett Gibb:
We have affiliation instructions on the Commons. We have it on the eSubmission page. There are step-by-step instructions there, and we actually have it on the video instructions that was on the slide set; we have a walk through of affiliation on video step-by-step for you.

Chuck Selden:
Okay. Is there a Parent announcement for every grant mechanism?

Suzanne Fisher:
No, there is not. And there probably never will be, but there are, and will be, Parent announcements for the very common grant mechanisms such as the R01, the R03, the R21 -- when we get to the common Fellowship mechanisms, the T32, I would expect, would have one. The Ks, the common Ks. Actually, we have the equivalent of Parent announcements for most of those now. The one that's really going to be new and different to people will be the R01.

Chuck Selden:
Next question: Do you have to provide the credential for Senior and Key Persons other than the Program Director or the Principal Investigator?

Marcia Hahn:
Not at this time.

Chuck Selden:

Can you explain the differences in the checks that Grants.gov does on the application compared to those done by the NIH?

Megan Columbus:
Sure. Grants.gov checks for any of the business rules that are common to all of the agencies that are using the forms. All the mandatory fields must be completed, the DUNS number must be appropriate, and the application must be virus-free. NIH checks the application for compliance with our business rules, with our application instructions, and for the instructions that are in the Funding Opportunity Announcements. Those NIH-specific requirements are not requirements that would be known by Grants.gov.

Chuck Selden:
Must the grant application be error-free by the submission deadline?

Megan Columbus:
Yes. Oh, actually, no. No. Not at this time. The application must be error-free in order for it to be finished in the submission process. It must be submitted by 5 p.m. local time to Grants.gov, and then there's a one-week correction window in order to address that error.

Marcia Hahn:
But don't get too used to that one-week correction window because that will go away.

Chuck Selden:
When submitting a changed or corrected application before the submission deadline, do we still need a new cover letter?

Suzanne Fisher:
Yes, because we really need to know that this is one that we've seen in some form before and is coming in again, and you need to explain in that cover letter what you've changed. And as Marcia has said before, if you had information, say about a request, make sure you keep that, because your Changed/Corrected at one point is going to replace the previous one, and so don't assume that we have the previous information in the cover letter.

Marcia Hahn:
Just a clarification. That's assuming that there was a cover letter that came in with the first submission. If you didn't send a cover letter in initially, and you're still before the submission time, then you don't need the cover letter just because it's Changed/Corrected. You only need it if it's Changed/Corrected after the submission. But they can send in Changed/Corrected applications before the 5 p.m. as long as you haven't already sent in the cover letter. But if you've sent the cover letter in initially, yes, you have to revise that cover letter.

Megan Columbus:

We aren't really encouraging, however, people to be editing through the eRA Commons, you know. We don't want the PI to submit three times and decide that, you know, they need to tweak their Research Plan a little bit. It's going to provide unnecessary strain and volume on the system and will slow things down for everybody. So we understand that that might on occasion happen, but we wouldn't that to be a regular practice.

Chuck Selden:
Do the Principal Investigator and Signing Official require separate accounts in the Commons, even if the Principal Investigator and Signing Official are the same person?

Scarlett Gibb:
Yes, they do. The Signing Official has to have a separate account from the Principal Investigator. This is the one time you need to do that. Also, in general, you only need to have one role per account, so if you are an assistant, that's all you need. If you're a PI, that's all you need. If you're a Signing Official, that's all you need. So one role per account usually works. There are a couple of exceptions: Internet-Assisted Review and Financial Status Reporting.

Chuck Selden:
How will supplemental and additional correction material be submitted after the application submission, and how will they be accommodated?

Suzanne Fisher:
Well that's a good example of something that's not changing. Just as it is on paper, if you find that there is something that was not correct in your application, or some late-breaking event, you need to contact the Scientific Review Administrator. Of course you'll find that person's name and phone number and contact information on the eRA Commons, and you need to contact the SRA, and getting in that additional information is at the discretion and instruction of the SRA. Nothing's changed by going to electronic.

I think, as I may have mentioned before, this will be just an add-on to your application. I guess that is one that is different. In paper, you can sometimes substitute pages. We do not have that ability in the electronic, so it will just be, "here is a new page 22 to replace the one that has a problem or whatever."

Chuck Selden:
Okay. Does the Program Director or Principal Investigator have the option to reject the application?

Scarlett Gibb:
No, they do not. The Signing Official has that obligation and option. It is because of the signatory authority of submission that -- I think Marcia is going to speak to it a little bit more.

Marcia Hahn:

I think it's just another example of where it will open up a great line of communication at your institution, between the PI and your signing officials. The Signing Official is the one with the physical authority to hit the reject button. Of course they would do that in consultation with the Principal Investigator.

Chuck Selden:
If you submit a proposal by 5 p.m. local time on the receipt date, and receive warnings and want to correct the application, is sending a corrected application within the next two business days still considered an on-time submission, or will the corrected application be considered late?

Suzanne Fisher:
No, that'll be on time. That's why we're giving you the two days, is to deal with those. Because you got it to Grants.gov on time by 5pm.

Megan Columbus:
But remember, you're going to need to reject your application, and you actually have more than those two days to submit. We would encourage you to submit as quickly as possible, but you have the whole one-week correction window. So there's two days during which time you would need to stop the application from moving forward in order to submit your corrected application.

Chuck Selden:
A scientist will move to my institution, and has a grant pending. Should we process the change of institution for that Principal investigator now, and can we do that electronically?

Marcia Hahn:
No. I would recommend you just wait, and the PI and you need to work directly with the Grants Management specialist in the institute. There's no point in dealing with the change-of-institution application if it's not going to be funded. If it hasn't been reviewed yet, then you need to work directly with the Scientific Review Administrator. They need to be the ones deciding whether or not they want a change-of-institution application before it goes to review. So it's really going to depend on the timing and where that application is in the process, as to who you talk to. But I think that's an opportunity for you just to start a dialogue with someone here at NIH, wherever it is in the business process, before you make those decisions. Right now, though, there is no ability for us to receive that change-of-institution application in electronically, so we would still need to accommodate that in a paper world.

Suzanne Fisher:
Yeah. If it's pre-review, it is very important to inform the SRA so that the review committee can be informed. Certainly, scientific research is basically a small town -- it is field by field. And if someone is moving, you know, that word spreads pretty well, and you don't want any confusion at the review meeting. "I thought that person was moving

so-and-so in three months. Why is the application still from the former place?" So definitely pre-review, get in contact with the SRA.

Chuck Selden:
Okay. A presenter noted that investigators have one week to address errors, one week after the receipt date. If it takes two days for Grants.gov to process the application, that leaves five days for the correction. Does the one-week period mean literally seven days, or one work week?

Megan Columbus:
It means fivebusiness days.

Chuck Selden:
Five business days. Okay. When an application is downloaded from a Funding Opportunity Announcement, are all the required components automatically included, and will the downloaded application contain components that will not be used to address that particular Funding Opportunity Announcement?

Marcia Hahn:
Yeah. All the mandatory documents will be in that application package as well as the optional ones. Let's take the R01, for example. You're going to see, in every one of those, two budget options, because for the R01 parent, you could be submitting a modular or you could be submitting a detailed budget depending on the dollar level that you choose, so both budget components are in that application package, but you only need to pick one. Likewise, the cover letter is always there as an optional form. You don't always have to use it, but there are cases that we've already talked about where a cover letter is required. The Sub-award budget attachment is another component that's always going to be in there if you had a detailed budget in there as well, but that's an optional form, and you only need to use it if you truly have a detailed budget that also includes a consortium budget. So yes, there are always going to be some budget components in every package that you don't need to use, but they're there in case you are putting together an application where those are required.

Chuck Selden:
We heard rumors about the transition from the IBM work forms, the PureEdge, to Adobe forms. Can you elaborate on that transition of form types, including the time frame, and give us an idea of when we might be able to test such a solution?

Megan Columbus:
Sure. My apologies for not mentioning this earlier. One good news for Mac users is that Grants.gov is moving to an Adobe e-forms solution. They're going to begin -- they're in the process of making that transition internally, now, transitioning the forms from the PureEdge forms to an Adobe e-forms. They anticipate completing -- they anticipate completing much of that by April of 2007. Agencies have until October to transition everything from PureEdge forms to Adobe forms. It's unclear, right now, when agencies are going to have an opportunity to test that, and it's unclear right now when that's going

to be available for System-to-System folks to begin testing those forms. And it's not until NIH gets some time to be able to test that we'll be able to plan our transition off of the PureEdge to the Adobe, because we want to do it in a way that's as least disruptive for applicants as possible. What it will require, though, is, once that change is made, everybody will need to download the new version of an application form, that will then be an Adobe-based form.

Chuck Selden:
Can a Principal Investigator delegate in Grants.gov and the eRA Commons so that his grants assistant can help with the mechanics of assembly and check the assembly of the application for accuracy?

Scarlett Gibb:
Let's start with Grants.gov. The application currently, if you're using the PureEdge form, allows for passing it around, basically. How you workflow it needs to be up to your institution, and I would suggest you put in some versioning controls. That allows for assistance, but there is no actual delegation of authority because the PI does not have an account in Grants.gov. In the Commons, delegation of your personal information can be made to an assistant so that they can update your personal profile, and delegation of e-SNAP can be granted to your assistant. But -- yes, but not reviewing the grant application or a summary statement or score, so that has to be done by the PI and the SO.

Chuck Selden:
Please discuss where to get the information on cognizant federal agency as requested in item H of the budget.

Marcia Hahn:
That's your indirect cost information. That's that section of the budget where you're providing the indirect cost information. And your Office of Sponsored Programs should know who your cognizant agency is, but for most cases -- for many of our grantee institutions, it's HHS. For some it may still be the Office of Naval Research, but your Office of Sponsored Programs should know that answer.

Chuck Selden:
In the SF424 forms, where and how do we designate Multiple-PIs for the project, and are all senior and key personnel automatically considered as PIs?

Marcia Hahn:
As I mentioned when I went through the forms, there's a couple of places where you specifically address Multiple-PIs. First off, the contact PI is who you indicate in item number 15 of the cover component. Then, in the Senior/Key Person component, this is where you would list all PIs, and you want to list them first before you would list the other Senior/Key Persons, and each person that you are designating as a PI needs to be assigned the PD/PI role. There's a list of values there for project role, and everyone in the Multiple-PI team needs to have the role of PD/PI. Reminder here -- anybody with that role, you also need to provide their Commons User ID. So for applications that are

coming in under the Multiple-PI model, all PD/PIs must be Commons-registered, and you need to provide that Commons ID in that application.

And then, if you look back in the Research Plan, there's a separate section of the Research Plan, now, that includes the Multiple-PI Leadership Plan, and that is also required -- and in fact is a system validation, so that if you -- it's item number 14, Multiple-PI Leadership Plan. If you have assigned more than one person the PD/PI role in the Senior/Key Person component, it's going to validate to make sure you've added an attachment back there in the Research Plan for the Multiple-PI Leadership Plan. The system will not allow -- it will be an error if those two -- that validation doesn't pass. So there's a couple of places in here now that we've intentionally put into the process to accommodate the Multiple-PIs. I encourage you, if you have more interest in Multiple-PIs, I encourage you to also read that Guide Notice that came out the same -- about two weeks ago, in the middle of November, where NIH announced more specifics on expanding the Multiple-PI as a standard option for any mechanism that has transitioned to electronic submission starting in the new year.

Chuck Selden:
For an appendix of an application, if you have paper copies of documents, such as signed letters of support, do they need to be scanned and uploaded, or do they have to be converted to PDF?

Marcia Hahn:
Yes to both. [laughs] You need to scan those, and in the scanning process you can convert them automatically to PDF to upload them. So they do have to be a PDF attachment, but that is the case where it's okay to scan it. That's not an example of where we're going to want to try to mine that data in any way, so letters of support certainly are a classic case where it's okay to scan, convert to PDF at the same time, and then attach.

Chuck Selden:
So it doesn't have to be optical character read?

Marcia Hahn:
Correct.

Chuck Selden:
Can movies be embedded into an R01 grant application?

Suzanne Fisher:
We wouldn't advise you to do that at this time. For one thing, it's probably going to make for a very large application, which you might have trouble dealing with. We don't expect Grants.gov or NIH to, but you may have trouble sending it. Movies very special, sort of unusual graphic features -- you should discuss with the SRA after the application has been submitted and assigned. The new appendix instructions, which came out this fall, also addresses sort of the standard items that people might include in an appendix, but if you have some very unusual item, you know, a sample heart valve or something,

obviously you're going to have to contact the SRA and find out how they would like to get that information.

Chuck Selden:
When we get a notice of a change in a Funding Opportunity Announcement-specific application, if we have already done work on the application, is there a way to update the application without destroying the work we've already done?

Megan Columbus:
So, the work that you've already done on the Research Plan, all those PDF attachments will stay the same, but you will need to start filling out a new application form, and unfortunately there's no way to automatically transfer that information from one form to another. We have hopes, and we're certainly making sure that Grants.gov understands that especially our community, since we have Funding Opportunity Announcements that can live for three years at a stretch, it's important for us to have a functionality that allows an export feature from one application form to another. We're hoping that the Adobe e-form solution may be able to accommodate that, but I don't have enough information yet to tell you for sure that it will.

Chuck Selden:
Who do I contact, after a few days, if my application has not appeared in the Commons, and what can I do, and will it be too late?

Scarlett Gibb:
You can contact the eRA Help Desk. We will start the process. We will need to know your Grants.gov tracking number, and our preferred method and the method that's going to get you the quickest results, is the web ticket, because it's going to ask for all the information and we can start our research process quickly. It will not be late if you submit it by deadline time, which is 5 p.m. local time, deadline date. If it was after that then it is late.

Suzanne Fisher:
I think it's also important to state that, in the rare cases when there's been truly a government-system problem, either at Grants.gov or at NIH, if there is something about one of our computer systems that caused the problem in your application, Scarlett's office keeps a special list of those, and those will never be penalized. You know, if you are the lucky person to uncover an unusual bug that we didn't know we had, or just some strange thing, we're not going to penalize you for a problem on our end of the computer.

Chuck Selden:
As an investigator, or a Principal investigator, how will I know that my Authorized Organizational Representative, my AOR, has actually submitted my application?

Megan Columbus:
You could talk to your AOR.

Chuck Selden:
Talk to the AOR.

[laughter]

Megan Columbus:
We actually -- we do understand that PIs really want to be able to track their application from the beginning to the end of the process, and one of the things we will be suggesting, and have suggested in the past, to Grants.gov, is to see if the PI can also get an email. The trouble is we need to make sure that all the agencies have that same need, and so it's that consensus-building that needs to happen in order for that to occur.

Marcia Hahn:
And remember, once it gets to the NIH site, then the PI does get an email. They don't get the email -- emails, excuse me, plural, from Grants.gov, but they do get the NIH-based emails. So t that's also a clue. But I think this is another opportunity, when I talked about a need to develop your new business processes with your institution, this is one of those things that you need to put in place, some sort of communication tool for letting the PIs know when that submit button has actually been pushed.

Chuck Selden:
I downloaded the SF424 form online through PureEdge a month ago. Are those forms still current?

Megan Columbus:
If you downloaded the form from the Funding Opportunity Announcement that you intend to apply, then yes.

Chuck Selden:
Okay.

Megan Columbus:
But you need to make sure that you didn't decide you were going to check out the forms, and so you pulled it from any opportunity, but you really want to apply to a different opportunity. So I would suggest that if you're going to play with the forms, which I would recommend doing, go to the parent R01 announcement and pull those down, because then if you make a mistake and you hit "submit," we'll get it and we'll be able to deal with it.

Suzanne Fisher:
If I could just point out -- right now, let's say an institute wants to issue a program announcement to encourage research in a particular area, and they want to allow R01, R03 and R21 applications, just because they want to give lots of different kinds of investigators the opportunity to submit, that's going to be issued as three separate FOAs, since there are different budget limits and page limits and appendix limits and things like that for those three. As part of our validation process, as part of making sure you get the

correct form package, they will issue it as three separate FOAs. They'll generally be in a suite with consecutive numbers, and so you have to be very clear that you get the right one. It may be, you know, PA0721, 22 and 23, and the science text is going to be the same, but one's going to be -- each one is going to be for a different mechanism. And if you mean to do the R03 and you grab the R01 you're not going to get the right validations and warnings and things like that, so it's very important that both Principal Investigators and Offices of Sponsored Research and other people who help them make sure early on that you've got the right match and then stick with that one.

Marcia Hahn:
And just to follow on that a little bit, we just started posting the R01 announcements about three weeks ago, I guess it's been, and so we're not done yet, and in many cases the institutes are still in the process of getting those converted, so if you know you are trying to respond to a Program Announcement for an R01 that is still written using the 398 terminology, just contact the institute, because, in many cases, the institutes will say to go in through the Parent Announcement, the new R01 Parent announcement. So you just need to have a little bit of a dialogue. If you find there's an opportunity out there that you think you are going to respond to, and it's the R01 and it hasn't been converted over yet into 424 language with an application package attached, just call the institute to find out where they are in that process or if they're planning on transitioning it over. In many cases, they're probably going to discontinue that announcement and have you come in under the Parent announcement, so you just need to ask the question.

Chuck Selden:
Can a single PI submit more than one grant proposal at a time, and are these different Funding Opportunity Announcements but the same deadline? What if they're different FOAs and one deadline? So, submitting two R01s in the same time.

Suzanne Fisher:
As long as they're scientifically distinct, yes, but you wouldn't submit the same science to both the parent and the topic-specific R01. Again, nothing's changed about the policy or the practice there just because we're having an electronic submission. And we have FOAs with the same dates and FOAs with different dates. I mean, we still have -- our blessing and curse is that we have lots of opportunities out there for you. That's the blessing. The curse is sometimes figuring out which is right for a particular investigator and science.

Chuck Selden:
When the PDF files are attached to the grant form, are they just links or are the files actually incorporated into the grant file?

Marcia Hahn:
The file itself is actually attached, and you'll see that. As you'll notice, every place next to the "Add Attachment" button, there's a blank space, and what it does is put the file name of what it is you've just attached. That's your other opportunity to do your double-check to make sure you've indeed attached the correct attachment there, and not, as one

person said, your son's homework, which has come through, or the Application Guide has come through as an attachment. We have that, thank you. We don't need that as part of -- and it's too big. So take that time to review those attachments. Even before you hit the "Submit" button, you have a chance to double-check that the name that you've named that file of what you've attached is truly what you want to attach.

Chuck Selden:
What enhancements are planned to the eRA Commons to assist with electronic submission?

Scarlett Gibb:
A variety of enhancements for performance were deployed in December -- November. That version contained many back-end performance enhancements that allowed it to go faster. We've discovered -- we've monitored, and they are -- the system is running at improved performance, and we also put in some enhancements for the PI screen so that they can see -- better utilize the status for their application, and we made a big fix -- there was a bug in e-SNAP and we did fix that bug. If you are still experiencing -- you find your data is still not quite right, please let us know by reporting it to the IT web link. We'll get right on it, but we believe we caught them all. And our future deployments will be to enhance the e-SNAP to make it compliant and to put those changes in that Marcia was speaking about earlier, and a few other enhancements on performance, and some other things down the road we are still looking at.

Chuck Selden:
Okay, this question's about the credential field on the Senior/Key Person form. Since this is a required field, and that means the application will generate an error if it's not filled in, why is this field not yellow?

Marcia Hahn:
Because it's only required for NIH. Keep in mind the Senior/Key Person component is one used by all the federal agencies that use the R&R, which is about sixteen different federal agencies. To my knowledge, NIH is the only one that has that as a required field, so that's why it couldn't be required in the form itself, because not all the agencies require something be put into that field. In this case, it's an agency-specific requirement, so that's where it's important for you to follow the agency-specific instructions.

Chuck Selden:
So -- so Grants.gov sends a confirmation email only to the AOR, while the Commons sends to both the Signing Official and the PI?

Megan Columbus:
Yes.

Chuck Selden:
Are other and pending supports submitted upfront, and not in a Just-in-Time manner?

Marcia Hahn:
We have not changed our Just-in-Time practice whatsoever. Unless the Funding Opportunity Announcement specifically states that it needs to come in at the time of submission, you do not need to include that as part of the initial submission. It would be requested and provided later through the Just-in-Time process. That business process has not changed.

Chuck Selden:
What are your suggestions to transmit the final document with all the attachments to the AOR, so that they can sign it? This is like an eternal business practice at the applicant's end.

Megan Columbus:
I know that some institutions use, kind of, electronic drop boxes, and these sometimes are emails that point to a shared network drive so that it alerts the AOR that the application is complete and available to them. Institutions at many of the professional societies are exchanging ideas because this is new for everybody, so I would strongly encourage you to network with other institutions that do business in similar ways, because I think you'll find that they provide a whole lot of potential solutions for you.

Chuck Selden:
Are there no headers and footers page numbers on the Research Plan file -- or as there are no headers and footers, how would you recommend that the PI identify changes and revisions in a resubmission? Say there's a change on a certain page, but that's not numbered.

Suzanne Fisher:
The headers and footers and the page numbers will be in the assembled image, so you won't put them in when you're sending the application electronically, but as you will see when you go on the Commons and look at the e-application, through the magic of computers, there will be headers and footers and page numbers, and so when a PI is doing the introduction for an amended application, they can refer to that. Most people also organize their Research Plan into sections and subsections, and so they could also refer to it that way as well.

Chuck Selden:
Okay. Please distinguish between weekdays and business days.

Megan Columbus:
Weekdays include holidays. Because holidays don't always occur on the same date every year, the electronic systems, when you program, you know, the two days to be able to view an application, certainly there are some that always come the same time every year, but many do not, and some institutions observe some holidays that others do not, and so weekdays are actual weekdays and they include holidays, so, you know, for those folks who had submissions due right before Thanksgiving, their twoweekdays may have come the Friday after -- or two weekdays may have come the Friday after Thanksgiving.

Marcia Hahn:
Chuck, could I circle back to the previous question about revision -- or marking any amended text? There is actually a separate section of the Application Guide that gives you specific instructions on that. It's section 2.7 that specifically addresses how you should deal with resubmissions, and it includes guidance on how, in the Research Plan, you should clearly bracket or indent or change the topography somehow, so, again, instructions are provided in the Application Guide specifically to address this. You also have the introduction that you have to add there as well, so you've got instructions in the Application Guide for that specific issue.

Chuck Selden:
And that introduction would be the cover letter?

Marcia Hahn:
No.

Chuck Selden:
That's a different kind of introduction?

Marcia Hahn:
That's the introduction to -- for resubmitted applications that's a separate part of the Research Plan. A required part, yes.

Chuck Selden:
Now, for the Senior/Key personnel component, do we need to list in alphabetical order, or combine them with other significant contributors, or do both of them need to be alphabetized separately?

Marcia Hahn:
This has generated a fair amount of discussion within NIH as well, because we've had a longstanding recommendation that Senior/Key Persons, or what used to be Key Personnel -- be in alphabetical order. We realize with this new component that can be quite problematic, particularly if you get to the last person and realize Professor -- Apple, you forgot. So we plan to relax that requirement to a degree, but keep in mind that whatever order you place them is the order that the reviewers will see them because we put the application together in the order that it's presented in the Senior/Key Person component. I think that becomes more critical now that we've used the expanded component, where it allows up to 40 individuals to be put in as structured data. One of the form functionalities that's a little bit frustrating is that you can't go back and delete and reorder very easily, and so we're trying to help out with that by relaxing the requirement for alphabetical order, keeping in mind that whatever order you do put them in is how the reviewers will see them, including the biosketches. So those will get out of alphabetical order as well. Anything else on that one?

Megan Columbus:

The only other thing is, we, again, provide continual feedback to Grants.gov on ways they can improve the form functionality, and so this, again, is on our list for them to work on.

Chuck Selden:
Now, we have a lot of questions. We probably won't get to them all, but let's try to go on the succinct side from here on out, and we'll see what we can do. Right. [laughs] In the Research Plan, if there is an overall page limit, does it cover the text only, or the actual document pages? Since each section has to be started on a new page, what would be a single ten-page document could end up being twelve pages when separated.

Suzanne Fisher:
We realize that, and that's why, if it is, say, the 25 pages that's currently allowed for the R01, if you submit 26, 27, or 28, you will get a warning, and beyond that it will be an error, because we realize that since each new section starts on a new one, there should be white space. That's why the best way to do this, the way that really makes most sense, is to write your Research Plan for whatever page limit is allowed as a single document. Make sure it's within 25 pages, or 15, or ten, depending on your mechanism, and then break it up. That's -- you know, if you get in a little bit more, you may think you're doing a good thing, but I don't think you're going to make the reviewers very happy. It's one of those things that it may seem like a good idea at the time, but in the long run it's always best to follow the rules.

Chuck Selden:
Can you please clarify that Progress Reports will not be submitted on Grants.gov?

Marcia Hahn:
At this point in time, NIH does not plan to require that, but keep in mind there is another federal-wide initiative that we have not addressed here at all, that is trying to come up with a common set of data requirements for Progress Reports. One of the features of that is the submission part, and that's still an unknown, so while NIH does not plan to require those through Grants.ov, we will need to wait and see what happens with that federal-wide initiative as to whether or not that will be what is selected as the transmission vehicle for Progress Reports in the long run.

Chuck Selden:
If the eRA Commons finds an error, what specific steps must be followed, like, do I reject the application with the error? And when do I submit a corrected one?

Megan Columbus:
If you get an error, what specific steps you have to take. You get the error. You need to go back to whatever computer at your home institution has your latest draft of the application that was submitted. You correct that data element. Your AOR submits that back to Grants.gov. You track it through to the Commons, and then you review the application image in the Commons. You complete that process of submitting it and

getting an error-free application within one week, and then you have two days to view the application.

Chuck Selden:
Do you see all the errors at once, or do you fix them one at a time and resubmit?

Megan Columbus:
You see virtually all the errors at once. There's a couple errors that stop the error checking, one of which is not including a credential, and so it's also possible that you will address an error that will allow the computer to check further, so if you didn't have human subjects noted the first time, and you do note it the second time through, there may be additional information the computer looks for that you may not have included.

Scarlett Gibb:
You do not get the reject button, to refuse, until you actually have an image, so if you have errors, you will not have the opportunity to reject.

Chuck Selden:
Okay. How should we include tables and figures in the Research Plan in the online submission? Are they separate attachments?

Suzanne Fisher:
No. They need to be included in the text. You need to embed them, if you will, in the text appropriately. There are instructions in the Application Guide about resolution and things, and you have to realize that what you put in there is what the reviewers are going to see, so if you shrink it down to something really tiny, again they're going to have a great deal of difficulty actually seeing those beautiful gels or micrographs or whatever.

Chuck Selden:
Okay. What would be the procedure for a PI to submit supplemental material on an application that has been successfully submitted electronically?

Suzanne Fisher:
Contact the SRA.

Chuck Selden:
Good. That was a fast one. What is the differencebetween Signing Officials and the AOR, the Authorized Organization Official, and who really signs it?

Scarlett Gibb:
Well, the difference is, basically, an AOR is a term that Grants.gov uses, and we have not been able to transition over to that in the Commons for Signing Official, so that's the term in the Commons. They can be the same person, or you could actually designate different people, but in general they have the same authority, which is to submit on behalf of the institution.

Chuck Selden:
So I'm working on an SF424 on my local hard drive, but my AOR is eighty miles north in another city. The AOR must click the "Submit" button to submit my application, but how does that happen? How does my AOR get my application, or access to it, or at least some notice that it's ready to submit? Is there an eRA Commons process for that, or is that all external to the eRA Commons? Do I have to email the AOR?

Megan Columbus:
Application preparation processes are defined by the institution, so email, shared servers, the same ways that you would work remotely with anybody at your institution doing anything.

Chuck Selden:
Okay. Let's see. That one we've asked already. Please clarify the week window, and why will it be going away?

Suzanne Fisher:
Okay. The one-week, five-businessday correction window was put in because we realize that this is a new process. It's a new process for us and you. And certainly, a year ago when we were first getting these, we tried very hard, we were not quite sure what to expect, and so we are trying to give some understanding and leniency the first time. Certainly our experience, as mechanisms come in more than one round, it gets simpler and simpler and faster and faster and it takes fewer tries each time. It will go away because one of the major hopes that NIH has about going to the electronic process, is that will allow us to ultimately significantly shorten the submission-to-referral-to-review-to-award process. Right now it's generally nine months or longer. We would like to have that be much faster. The pace of science is moving fast. We want to get the results, and hopefully the award money, out there faster.

Chuck Selden:
When submitting a renewal to an R01 grant, will the PI have to register on Grants.gov and the Commons, or will the system recognize this person again?

Scarlett Gibb:
Again, the PI does not register on Grants.gov, only the AOR. However, in Commons, if they already have a current registration, one-time registration is all you need. One account, one-time registration. Yeah, just don't forget to put it in the application. The ID has to be in the R&R Senior Key Person -- and keep up your information, so if you've moved from institution or you've changed your email address, please change it.

Suzanne Fisher:
Or, an important thing, we'll have people who have moved from assistant professor to associate to full professor and never bothered to update their information, I think you'd want to share that.

Chuck Selden:

CSR will consider late applications up to two weeks after the deadline, but will error corrections be considered a valid reason for submitting late applications after the one-week grace period is no longer allowed?

Suzanne Fisher:
There will still be a late application policy. It was recently updated in August. It will be updated again probably this week or next week to account for our increased use of spreading submission dates and the multiple PI. But the one-week or two-week window, depending on the date -- the type of application still is in effect, and when the week correction window goes away, I don’t know -- we will still have a late policy. Whether those windows will still be the same in a couple years when we we’re trying to seriously shorten everything, we’ll just have to wait and see.

Chuck Selden:
Okay. Is it better to submit an unsigned cover letter or a signed and scanned PDF version? They want to have an image of the signature or not.

Suzanne Fisher:
The cover letter is something that we are probably going to want to text mine to get your request for assignment to the review groups and/or ICs. That is not a structured data field, and so scanning it probably is not the best way to go, in that sense. Send it in a way that it will make it easier for us to data mine.

Chuck Selden:
Will the Grants.gov submission deadlines always fall on regular federal business days, and if not, will the submission date always automatically be extended to the next federal work day.

Suzanne Fisher:
Yes. For standing dates, such as February 5, it’s the same as now. If that falls on a weekend or a holiday, it’s extended to the next business day. Policy is not changing that way.

Chuck Selden:
Is a biosketch attachment required of all Key Personnel or just the PI?

Marcia Hahn:
It’s actually a required attachment for anyone you list in the Senior/Key Person component, so for NIH that would also include anyone that you might designate as an “Other Significant Contributor” that you’ve listed in that section.

Chuck Selden:
If a PI accidentally registered twice in the eRA Commons, but with two separate user ID’s, what should the Organization Applicant do to drop one of them?

Scarlett Gibb:

Get in touch with the Help Desk. We will work with the applicant to get the one that they wish to use fixed and then to roll all the information into that.

Chuck Selden:
I'll read that one while you answer another one. It's kind of complicated. Let's see. Is there a specific form for the Research Integrity, or is it just a letter? Research Integrity, is this a certification, a check-off?

Marcia Hahn:
That's one of the standard assurances that is complied with -- I'm not sure I understand fully, but right now in the Research Plan component, there's not a separate section that specifically addresses that. That's just one of the overall institutional assurances that you comply with every time you sign and submit any application.

Chuck Selden:
Okay.

Marcia Hahn:
If we didn't answer that, maybe you could send a follow-up question, because I'm not sure if we got the right question.

Chuck Selden:
Can you attach a draft budget narrative in order to proceed on to the next period budget pages, and then, before final submission to Grants.gov, replace the draft budget narrative with a final version?

Marcia Hahn:
Yes, you certainly can.

Chuck Selden:
If there is an error when submitting to Grants.gov, and it was corrected when it gets to the NIH, does the clock start again? That is, the two days to find out if there is an error, and one week to address the error?

Scarlett Gibb:
Could you repeat the question?

Chuck Selden:
If there is an error in a submitted grant, but then it was corrected -- now it says "when it's corrected when it gets to the NIH." I guess that would be an error in NIH verification that is -- two day -- are there two days to find out if there was an error, plus a week to address the error?

Megan Columbus:
All right, let's go over the timetable one more time. So, you submit your application to Grants.gov by 5 p.m. on the receipt date.

Suzanne Fisher:
Successful submission, which means overcoming Grants.gov errors by then.

Megan Columbus:
If you -- that's true -- if you have no errors in your application and you just have warnings, you will get an application image in the Commons. Two days will pass before that application image gets submitted to Suzanne's shop for referral to a study section, okay? If you have errors, you will not get an image, so the two days does not yet pertain. If you have errors, you go back, you correct your application, you send it to NIH -- to Grants.gov again, NIH picks it up. At the time you have the application image, because you've addressed all those errors, is the time when your two-day clock will start in order to view your application. Is that clear?

Chuck Selden:
The person's in the audience, so…yes? Okay. Use the microphone behind you please.

Female Speaker:
There is no microphone.

Chuck Selden:
That's not turned on? Oh, it's gone.

Megan Columbus:
Or speak loudly, and we'll repeat your question.

Chuck Selden:
Okay, I'm sorry.

[low audio]

Suzanne Fisher:
To meet the 5 p.m. local time to Grants.gov, you have to successfully submit to Grants.gov, which means you cannot have any Grants.gov errors. Okay, you have to get it successfully completed at the Grants.gov level by 5 p.m. local time on the due date.

Megan Columbus:
So remember that Grants.gov is only checking for a couple things. It's checking for a virus. It's checking for DUNS number.

Suzanne Fisher:
You have to get it through the limited validations of Grants.gov by 5 p.m. by the due date to be on time. Okay. Then it comes to NIH. If there are errors, you have to correct those and you have right now, but not forever, the one week to work through the errors that NIH finds through our process. When, in the course of that one week, you get all of those fixed, and you get to image, then your two-day clock to look at the image starts,

and within those two days, you know -- one would think if you took several days to correct errors, the likelihood of needing to reject it at that point would be pretty low because you've looked at it so many times -- whatever. Yeah, but then, that's when the two day clock starts, once you get through all of the NIH validations and get a completed, assembled application image.

Chuck Selden:
Okay. Will Just-in-Time information be submitted through eRA Commons? In the past, we've been given the option to send a fax, email, or the Commons for Just-in-Time information.

Marcia Hahn:
At this point in time, submission through the Commons is still an option. There are some recognized improvements needed to that that we would want to put into place before we would make that a requirement, so you still do have the option of submitting it through other paper, hard-copy vehicles, but certainly, if you are able to use the Just-in-Time in the Commons, that is the preferred method.

Chuck Selden:
How do you allow several people to work on the application, such as a budget person and the PI, in order to assemble all the form pages and get one version to the PI?

Megan Columbus:
You have to work within your institution to figure out the best way to share the document.

Chuck Selden:
What are the hours for the NIH Commons Help Desk or the Grants.gov Help Desk?

Scarlett Gibb:
The NIH Commons Help Desk is open 7am to 8pm Eastern Time, the Grants.gov Help Desk is opened 7 to 9 Eastern Time.

Chuck Selden:
Okay.

Scarlett Gibb:
Mondays through Fridays. I'm sorry. Mondays through Fridays.

Chuck Selden:
Can the Authorized Organizational Representative, after getting a request from the PI, reject an application that did not receive any warnings or errors? Could a cover letter be added to the changed application to explain the reason?

Suzanne Fisher:
Yeah, I mean the --

Chuck Selden:
So they've submitted and they want to pull it back.

Suzanne Fisher:
Yeah. It's submitted, they successfully got to image, and they discovered that they sent the penultimate version of the Research Plan. That would be grounds for rejecting it and then you would have to explain that in the cover letter when you go back through Grants.gov and get it through again.

Chuck Selden:
How much of the profile is the PI required to -- oh, go ahead.

Marcia Hahn:
But we have to emphasize, that is not to be used as a chance for last-minute word-smithing. There's got to be something fundamentally wrong in order for you to reject it. The reject should not be used for last-minute word-smithing.

Chuck Selden:
Okay. How much of the profile is the PI required to complete beyond the initial registration in the eRA Commons?

Scarlett Gibb:
As much of it as he can. Required -- he's not required to fill out anything other than what is required. There are certain fields in there starred in the profile, but we ask that they fill out as much as they can, because you never know down the road what you may need and what part of it will be used.

Chuck Selden:
If I've submitted early, prior to the deadline, and find a mistake in my Research Plan, like I left out a page or a figure, can I correct it?

Megan Columbus:
Within the two-day viewing window, yes.

Chuck Selden:
Okay. My submission deadline is the 8th of December, but you don't see it in the eRA Commons until the 11th of December. Now, do I still have one week after the 8th or one week after the 11th?

Megan Columbus:
One week after the 8th to address corrections. I'm sorry -- yeah. One week after the 8th to address corrections.

Chuck Selden:

The first day. Okay. In the past, I had to fill out my research sections and budget justifications on continuation pages, what should I do now?

Marcia Hahn:
The continuation page was nothing but a blank piece of paper. Now you have the opportunity to create it as a single document. You don't have a form page. There is no fill-in-the-blanks of text in there. You just create it in Word or WordPerfect, whatever is your favorite word processing package, and then split it up as necessary when it comes time to actually attach it.

Chuck Selden:
I registered all of our PIs in the eRA Commons. Do they need to register themselves again?

Scarlett Gibb:
No. No, you did a great job. Thank you.

Chuck Selden:
On the budget pages, where do you put payments to your research subjects? In Section E or Section F?

Marcia Hahn:
Oh, I believe we said that that would be under Section F in the blank lines. You have an opportunity there, and we have special instructions on -- that's where you should include information on patient care costs.

Megan Columbus:
They would find the answer in the Application Guide.

Chuck Selden:
Okay. So it was stated that we should not scan documents or convert -- that we should not, it says here, scan documents or convert to PDF, however, often we don't have an electronic format for appendix items such as support letters and forms. Our main means of conversion is scanning to PDF. Is it okay to scan non-electronic papers to PDF?

Suzanne Fisher:
Yes.

Chuck Selden:
Do you recommend that a PI use highlighting to indicate changes in a revised or a resubmitted application since brackets or lines in the margin can no longer be used?

Suzanne Fisher:
Well I think you can use brackets or margins if you're clever enough in your word processing program. We don't recommend you use highlighting, because you don't know -- especially -- the reviewers are increasingly looking at these online and you're not

too sure how that will show up, what they're looking at, so I wouldn't get too fancy that way.

Marcia Hahn:
In fact, that is part of the instructions in the Application Guide. It says "do not underline or shade changes."

Suzanne Fisher:
Underline is ugly. It just makes it really hard to read.

Chuck Selden:
In the budget section -- to get a clarification on the budget section -- as I understand it, the NIH requires the names for postdocs and grad students. Is that correct?

Marcia Hahn:
We do ask for some additional detailed information for those categories as part of the budget justification so that we can continue to check for the graduate student compensation limitation, and for overlap since we have a wide both predoc and postdoc fellowship program at NIH, we do -- that is one of our standard administrative checks.

Chuck Selden:
Where do you indicate "new investigator?"

Marcia Hahn:
On the cover page supplement there is the "new investigator" code.

Chuck Selden:
So where do letters of support and biosketches of collaborators, who are just submitting letters of support, go?

[low audio]

Where do letters of support and biosketches of collaborators -- maybe this means submitting them after application is submitted --

Marcia Hahn:
No. Well, if they are not considered Senior Key Persons, then a biosketch is not required. The letters of support, however, there is a spot in the Research Plan component for a separate upload for those. It is item number 16.

Megan Columbus:
Again, I'd recommend looking carefully at the Application Instructions, especially for the pieces of the Research Plan.

Chuck Selden:

We're down to our last minute here. We have few questions from the audience. We can address those online. But I would like to thank everyone for -- our teachers, for instructing, for everyone in the auditorium, for coming, for those who've tuned in on the videocast, and know that this session will be repeated at 1:00 Eastern Time. This session and the next one will be available on the videocast archive and will be on the training pages for the eRA Project in downloadable formats, maybe even podcasting. The slides with the take-home points are now on the website. They weren't in the earlier versions of the handouts. For those in the auditorium, those are available on the table in the back. And we'd like to thank Manju [spelled phonetically] Subramanya [spelled phonetically] and especially Stacey Kocher for their extensive work in the background to make this possible.

[applause]

Thank you very much. That's it. We'll be back in an hour.

[low audio]

[End of Transcript]