Updating Inclusion Data Transcript

Hi everyone, I'm Dawn Corbett. I'm the NIH Inclusion Policy Officer in the Office of Extramural Research, and today I want to talk to you about updating inclusion data for awarded research and development contracts.

I'm gonna start a little bit by reviewing the requirements for inclusion data in contracts. These have not changed.

We do have two policies on inclusion of participants and research. So first involves inclusion of women and members of racial and ethnic minority groups, and the policy requires that women and members of racial and ethnic minority groups be included in all NIH funded clinical research studies, unless there's a compelling rationale for exclusion.

In addition, any NIH defined phase three clinical trials must be designed to permit analysis by sex or gender, race and ethnicity, and then a subset of those and each defined phase three clinical trials called applicable clinical trials must report results of those analysis and clinicaltrials.gov and this applies to the applicable clinical trials, which are typically trials of FDA regulated products.

Our other inclusion policy is our inclusion across the lifespan policy. This policy is more recent and it applies to contract solicitations issued January 25th, 2019 or later. This replaced our inclusion of children policy, which we had in place prior to that point, and this requires that individuals of all ages be included in any human subjects research, unless there are scientific or ethical reasons not to do so.

The policy also requires submission of individual level participant data, and this is typically submitted in annual progress reports, but can be requested as frequently as needed and as required by the contract, the individual level participant data include the participant sex or gender, the race, the ethnicity and the age at enrollment of each participant.

This screen shows a spreadsheet which is actually a CSV file which is submitted with participant information. So in this example you can see that you have the race, ethnicity, sex or gender, the age and the age unit for each participant and the age unit can be provided in units ranging from seconds to years.

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And at the end of the year, we compile all of the inclusion data and we include them in several reports, which you can see here on the screen, including a bi-annual report of the Advisory Committee on Research on Women's Health.

We also provide an NIH RCDC inclusion statistics report which shows all of the inclusion data by research condition and disease category. So because you breakdown for each category and for each IC and and then each IC will present a report to their Advisory Council tri-annually and you can find all of those reports on our report website, which is linked below.

So what's new? So what's new is era has developed functionality to allow direct vendor entry into the human subject system or known as HSS. So, eRA previously did not have functionality that allowed vendors to directly access the system.

The data were entered manually by NIH staff. Typically they would be emailed to NIH staff to our inclusion operating procedures working group members, with an end of the year data call and then those individuals would enter the data into eRA.

But now we have functionality to allow the vendors to go in directly, and this functionality will streamline the process, and it also allows for secure data transfer.

So we don't need to email files back and forth and it harmonizes process used for grants and contracts.

New contract language for this requirement is expected to be implemented in 2024.

So this just shows you a bit about what the process will look like, and so with the new process, the contract vendor can make direct updates via the Commons so they can log in directly to the Commons. They do have to be registered in the eRA Commons in order to make these updates. Once in the Commons, they can pull up their studies and access the human subjects system directly via a link.

Of note, the human subjects system also interacts with clinicaltrials.gov it allows import and export of data into the system.

The data in clinicaltrials.gov are entered by the responsible party.

With that I will turn this over to my colleague Fernando to tell you a little bit about the new functionality.

Thank you, Dawn.

So thank you.

My name is Fernando and I'm an analyst with eRA so I will go ahead and show you how a vendor submits a human subjects information through the eRA Commons.

OK, so first I will be logging in as a PI, principal investigator or project director in the eRA Commons.

So from the eRA Commons login.

We start here and log in and we need first we need to find our contract information, so we'll we will click on the status link or tab up here and then we click on list of applications and awards.

And from our status result, we will find our contract.

And here will we see the information of all our components that have been awarded in our contract and as you can see the all the information here on the right hand side under available actions there's a human subject link and sometimes you may not see a human subjects link.

That that means that this component has not been set up to to include a human subjects data.

OK.

So we will go ahead and add a new study on our component #5.

So I will click on the link here.

This will open up the ASSIST portal and here's what we where will we will be entering a new study.

OK, so we have our contract information here and on the left hand side we have a component types and we will click on the plus sign under for miscellaneous and here we will find our component #5.

OK.

And as we can see the the title matches our component 5 that we saw in the eRA Commons.

OK.

So we first click on the HSCT post submission tab.

OK.

And we click on the edit button.

Now we will click on Add New Study.

And here we can start adding the information for our study.

I will name my study just Contract Study and I will name my study just contract study and for this study record of the first section is required to be filled out and you can see which questions are required by the red asterisk right here.

OK.

And we will answer these questions like this for now.

When you want When the clinical trial Questionnaire is is one question is answer is no.

That means that there is not a clinical trial and when all four questions are yes, that means the the study will be a clinical trial.

So for now, we'll leave one of these or two of these as no.

So this makes it not a clinical trial, OK.

And also we have this functionality if you have a NCT number for from clinicaltrials.gov you can actually enter it here and click populate and this will fill out the rest of the form very easily.

OK, so for now, as we can see, none of these questions are required because there's no red asterisk.

So this this form technically is ready to go, but we will go ahead and and add a new inclusion enrollment report.

So first we save and add report.

We enter a title for inclusion enrollment report.

OK.

These questions again, are required.

So we need to select some entries here and here we will have two tables the Planned and Cumulative enrollment tables.

And it's just to add some data here. See the the forms allow you to enter directly into the table.

This and there is another way also by uploading the participant level data attachment.

That's what Dawn was talking about before or with the with the CSV file.

So to be able to upload this this CSV file, first we wanted to download this template and let me click this button here and you see this will download a template in CSV format, which can be open in Excel.

So in Excel we see the format for this attachment.

OK, so as you can see, these are the entries that are allowed.

In this file, so I will recommend making when adding new entries.

Say you're adding a new person, that is, you know, patient umm, this Hispanic or Latino female, and it's just one year.

Uh, please make sure to do not end.

Do not change the format to one year.

Always keep the same format throughout the the form.

Because otherwise it won't let you to. It won't let you upload into the system, so just make sure to keep the same format when when adding new entries into the into this attachment.

So I'm going to add more attachments here or more more participants I mean.

And upload it into ASSIST.

OK so I have added 29 participants, so that's 30 -, 1 someone else to save this file.

OK, first I'm going to save this form.

And I'm going to upload the file that I just downloaded and edit, that will be this one.

OK.

As you can see, the table just reflected on the the changes that I made on on this on that attachment on this file, on this Excel spreadsheet.

And as you can see the total here is 29 participants.

So let's go ahead and save and release lock.

OK, so now that we've made all our changes to our study record, I am going to click Validate here from the left hand side and here we just want to make want to make sure that everything is good and completed so you can see all validations passed so that that means that this study record is is ready to be submitted.

So we go back to our previous screen and now now we need to submit this study.

So for that we need to click on update submission status.

And then we select ready for submission and then here you can just click continue or add a comment.

OK, so now our status has been updated and is ready for submission, so I will go ahead and click submit and one more time submit.

OK, so now our application has been submitted.

So that means our our program official should be receiving an email with this information.

So now let's say that our program officer has requested to make some changes to our study record and we will also you will need to go back to our to our study that we just submitted and make some changes.

So for that we would we go back to the status tab under our contract information and we'll click on the same human subjects link.

So for that we would we go back to the status tab under our contract information and we'll click on the same human subjects link.

So as you can see the status is now Submitted.

So if you try to go to the study record, umm. First, you'll notice that now you actually have a study ID, and now there's no edit button, however. So what we need to do is is actually change the status back to Work in Progress one more time, OK.

We'll go ahead and click this.

So now we're back in, in work, in progress.

So we can go ahead and and edit my study one more time.

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OK, so now let's say that we needed... We need to make this this study a clinical trial study.

So we will go ahead and click yes for these two questions.

So that'll makes it up clinical trial and I'm going to save this form.

And now let's say yeah, we needed to make some changes to our inclusion enrollment report.

OK, so let's say we're making some updates or there were some some mistakes on the on the on the spreadsheet that we uploaded.

So we will go ahead and upload a new data attachment file, so... So I will be uploading this file which has I believe 40 participants around 40 participants.

So you can see this one had 48 participants.

So now I'm going to save this form.

And now let's go ahead and click Validate.

OK.

As you can see, we do have a couple errors, so this is because we made our study a clinical trial and so keep in mind errors need to be fixed before we can submit our our application.

If you receive a warning, you can address the warning, but the system won't stop you from submitting the application.

So let's go ahead and fix these couple errors, so here we need to answer this question.

Is this an NIH-defined phase three clinical trial and is this an applicable clinical trial on their FDAAA?

So let's go ahead and fix those two questions.

OK.

The phase three clinical trial question is right here 4.1.D so I'm just going to say no for this one.

And then the FDAAA question is 6.6.

So for this, I'll, I'll just say no as well.

OK, now that we answered those two questions, let's validate one more time.

And now all our validations passed.

So let's go ahead and submit this one more time.

OK, so now our application has been submitted and again our program officer should be receiving.

So notification that we've made changes to to our study records so, so that's how you submitted a new study and how you edit an existing study through the era Commons ASSIST.

Thank you.