NIH Grants Conference PreCon Event, Human Subjects Research: Policies, Clinical Trials, & Inclusion

Day 2, December 7, 2022

Human Subjects System (HSS) Session

Dawn Corbett: Okay, welcome back from the break, everyone, and thanks for joining today's presentation which is focused on using the ERA Human Subjects System. During the next 45 minutes, our presenter will be highlighting some important information on this system and answering your questions. My name is Dawn Corbett. I'm your moderator for today's presentation, and I'm also the NIH Inclusion Policy Officer in the Division of Human Subjects Research within the NIH Office of Extramural Research. So now let me introduce to you our NIH expert on this topic, Dr. Rebecca Favor, NIH Human Subjects and Inclusion Policy Analyst, who is also within the Office of Extramural Research at NIH. Rebecca?

Rebecca Favor: Thank you, Dawn. So let's talk about the Human Subjects System. So the goals for today's session are to help you understand basically what the Human Subjects System is, or HSS, as we will be calling it for short just because the Human Subjects System is kind of a long name. So I want you to be able to understand what HSS is and describe the methods for navigating HSS. There is specific information that's required to be provided to us in the system if you have a study that is human subjects research that's not a clinical trial versus a clinical trial, and we'll go over that information, so you can understand those requirements as well as understand how to provide information and updates in HSS as well.

So to start off, let's talk about what's required pre-award for studies that involve human subjects research. So when you're filling out your initial grant application, there is a PHS Human Subjects and Clinical Trial Information form that needs to be completed for human subjects research studies. That form has five sections in it, and the sections that you complete are based on the type of study that you are proposing. So let's take a look at this table. The table outlines what's required for studies that do not meet the definition of a clinical research per NIH definition and those that do, and if you recall, the clinical trial designation is based on the response to four questions that are at the beginning of the PHS Human Subjects and Clinical Trial Information form. This is in section one, and if you answer yes to all four of those questions, your study is designated as a clinical trial. If the response to any of those questions is no, then your study is not designated as a clinical trial. Excuse me. So if your study is not a clinical trial, you're required to complete section one. You're generally also required to complete section two as well, except for some fields that are optional if your study meets the criteria for the exemption four. Section three is also generally required as well, and then there are a few fields that are not depending on the type of human subjects research that you're doing. On the other hand, if your study meets the criteria for a clinical trial, you're required to

complete sections one through four and then also section five in some cases. This is only if the specific Funding Opportunity Announcement that you're responding requests information in that section. Otherwise, that section should not be completed.

So let's now fast-forward to the post-submission environment, or in other words, once you're submitted your research, and you are in the Just-in-Time process. You've learned that you're going to get your NIH funding. Once you're in that stage, then you will be required to provide updates to your information as you go through your study. The information that you provided in your initial application is then pulled into the Human Subjects System, and that's where you're able to edit it, make updates to your studies and that sort of thing. The Human Subjects System, or HSS, mimics Assist. So if you used Assist to complete your initial grant application, the screens and the functionality will seem pretty familiar to you. It's important to note that there are also specific permissions that are required in HSS, just as there are in Assist, to help you or allow you to be able to update information. So you'll need to get with your signing official to make sure that the correct role was assigned to you for you to be able to provide the updates that you need. As a note, updates in HSS to your study records can be made at any time, even though at certain periods you'll be required, for example, annually to provide updates to your records, so that we know what's happening at the time of your progress report.

This diagram outlines how the Human Subjects System interacts with other modules and other application types that we have. So again, for example, at your initial grant application, you fill out the PHS Human Subjects and Clinical Trial Information form, and eventually that information is pulled into the Human Subjects System, so that you can then make updates. You can access this information during the time of your RPPR through the RPPR module or, as I mentioned, anytime by directly going to the eRA commons to make updates that way, and I'll show you the way that you access those systems, so that you can make the updates at those times. In addition, our Human Subjects System also interacts with clinicaltrials.gov, and this happens in two ways. So first, the information in HSS can be used to initiate your clinicaltrials.gov registration if your study is a clinical trial because there are some fields in your study record that are mapped or is the same as study fields in clinicaltrials.gov. Additionally, clinicaltrials.gov information that you update after you've registered can be used to update fields in HSS. That way you can make sure that the information that we have in your study record is the same and is up to date with your clinicaltrials.gov information. I'll talk a little bit more about exactly how you do that a little bit further in the presentation.

So first let's talk about how to access HSS. So the first way that you can get into the system is by going into the RPPR module. So if you've completed an RPPR before, there is a section, Section G4, that is designated for human subjects. Within that section, there is a human subjects link, and when you click on that link, you'll be taken into HSS. The page that you land on is the application information page, and this is within HSS and the summary tab. There's some general information about your grant there. So it'll list the grant number, for example, the name of the

PI, your organization name and the application status. So that's the landing page that you access when you first get into HSS that way.

The other method is to go in through eRA commons, and you go in through the status tab. So once you've searched for the list of projects that you have, you can access HSS through a human subjects link as well. For signing officials, it may look a little bit different than it does for PIs. So for example, for signing officials, you would click on the meatball icon, as we call it, or the dot, dot, dot that's next to the application ID, and you'll see a drop-down with some options for the human subjects link and a couple of other things. So you click on the human subjects link to go into HSS that way. For PIs, the human subjects link may be under available actions that'll be in the listing for your application or your award ID instead. Either of those will take you into the same application information page that I showed you on the previous slide.

So let's pause there really quickly to do our first knowledge check. So let's say that Dr. Cox has an RPPR that's due soon and needs to update the study record. What methods can Dr. Cox use to access the record, A: access to RPPR module and then click on the human subjects link, B: use the common status tab to search for the project and then go in that way or C: either is fine, D: neither is fine? I'll give everyone a couple of seconds to put their answer in the poll. All right. Looks like we have responses, and it looks like most people said C: either is fine, and that is correct. So even though Dr. Cox does need to update the RPPR, it's perfectly fine to first go in through the commons status tab and to search for the information that way or to go ahead and access the RPPR module and then go into section G4. Good job, everyone.

So now that we know how to access the system, let's talk about updating the information in the system itself. So the first thing that you'll want to do, once you land on the application information page and you need to make edits, is check the status that's listed on that page. So in the example here on the slide, the status is in Submitted status. When you're in submitted status, you're unable to make any edits, so you'll need to change that status to Work in Progress which is what is needed to make edits and to be able to go into edit mode itself. To do that, you'll click on the Update Submission Status button that's available under Actions under the panel on the left. It'll be on the left side of the screen. When you click on this button, a message box will open up that has a drop-down menu, and you can choose Work in Progress from there. Once you do that, you can click on the hyperlink text that says Continue Without Adding a Comment, or you can go ahead and add a comment, so you can note the reason that you're making updates, if you like, if that's important to you and your study team. Click Add Comment, and you'll save the information, and you'll save the status that you've changed it to.

So now that we've changed the status to Work in Progress, what information do you need to update? So for all studies, you'll need to update the inclusion enrollment data if you've begun enrollment on your study. You may also need to update the recruitment status or any other information that's required by funding IC or that's requested by a program officer. For clinical trials, you'll need to update the same information, but you'll also need to provide your NCT

once you register your study in clinicaltrials.gov. You'll also need to update the clinical trial milestones which are available in section six that are required starting at your first RPPR.

So to edit your study and provide the information that we just mentioned, you click on the HSCT post-submission tab that's available on that first application information page that you land on in HSS. When you do that, it'll open up a page that lists the study records that are available on your project. Then there are two ways to start making edits. So first you can click on the Edit button that's at the top of that screen. It'll then populate an Edit button in the listing for each study record, so you can click on Edit on the study record that you want to see, or you can click on View to view a particular study record that you're interested in first and then click on the Edit button that opens up when that study record opens. Either way is fine. There's more information about how to go ahead and edit your study record in the HSS online help chapter How Do I Edit Studies?, if you need more information.

So we've learned how to access HSS, and we now know how to update the submission status and begin to edit information. So let's talk specifically about updating the inclusion information in your study. To update the inclusion information, you'll need to access your Inclusion Enrollment Report. This is found at the end of section two within your study record. So if you scroll down to section two, you'll see an Enrollment Report section where it lists each of the Inclusion Enrollment Reports that you have. There's also an Add a New Inclusion Enrollment Report button. So this button is there, and it should only be used if you need to actually add a new Inclusion Enrollment Report to describe a population you hadn't described in your study before or to provide something new. You don't want to click that button if you just need to provide edits or provide updates for an already existing Enrollment Report. To do that, there will be an Edit button that's in the listing of the Inclusion Enrollment Reports for each of those that you have on your study. So click on the Edit button for the particular Inclusion Enrollment Report, and it'll open the report for you. Once the report opens, you'll see the listing for the different fields. So the study - the Inclusion Enrollment Report title, you'll see the buttons for whether or not it's an inclusion, describes an existing dataset or resource, whether or not it's a foreign or domestic study and that sort of thing. So all of those attributes will be there. You'll also see the planned enrollment table and the cumulative enrollment table for that particular Inclusion Enrollment Report.

Now, because of the Inclusion Across the Lifespan policy, all research that came in on applications January 25th, 2019, or later are required to provide individual-level or participant-level data. The way that this is provided to NIH is by completing a spreadsheet that we have available as a template for you to use to provide a line item describing each of the participants. So as you can see in this screenshot of the template, there's a column for race, ethnicity, sex or gender, age and then the age unit. In the template, there's some sample data provided, just as it is in this screenshot, that provides an example of how the information can be entered on the template. There are a couple of things to note about the template itself. First, the location, so you can access this template from several different locations, including in your Inclusion

Enrollment Report itself. There's a button that's located at the end of your Inclusion Enrollment Report that allows you to download the template. The template is also available from the inclusion policy websites and then also from the eRA HSS training web page. All these resources are listed at the end of the presentation. Secondly, the template is a CSV file, and it's very important for it to remain a CSV file when you complete the information. That way the system is able to recognize the file and upload it appropriately. If the file type is changed, you may receive an error when you attempt to upload your spreadsheet. Secondly, it's important for you to maintain the columns that are listed and not change the order around and make other format changes. Again, if that's done, then the information will not be uploaded correctly in the system, and you'll get an error when you attempt to upload. We have a tip sheet that's available to provide some of this information and also details about how you provide the race information, what variables or what names to use, what units you can provide for the age units and that sort of thing, and a tip sheet on several websites as well. This is also available at the end of this presentation as a resource for you. So it will be advantageous, or I would encourage you to open that tip sheet at the time that you're completing the spreadsheet, for the first time especially, so that you can make sure that you're entering the information in a way that the system will be able to recognize. Of note, you can manually list out each of the participants and type them in individually, or you can copy and then paste the information from another source into the spreadsheet, provided that you paste the information as values only, so that you don't copy any formulas or other formatting into this spreadsheet.

So once you've done all of that and you've gone through and made sure that the information is in there correctly and you've saved it, you can return to your Inclusion Enrollment Report and upload the attachment. There's an Upload Attachment button that's located at the bottom of the cumulative enrollment table. When you click on this, it'll open up an option for you to be able to choose the file from your computer and then upload the report. If the report uploads correctly, what will happen is that the cumulative enrollment table will populate aggregate information for what you've provided in the spreadsheet. If the upload does not go through, you will get an error message letting you know that it did not work, and it will also include some tips about things you'll want to check to see what exactly is causing the error within your spreadsheet.

Of note, you can also download the participant-level data once you've provided it initially to us. That way you can have a copy of what you provided to us and in case you need to go back and confirm all the information that was provided. Since this is cumulative enrollment data that you're providing to us, please note that you should make sure that you add participants as you enroll them to your spreadsheet, rather than only providing new participants to us each year. That will replace the previous participants instead of providing a cumulative list which is what you actually need to provide.

All right. So let's do another knowledge check. What items do you need to submit an Inclusion Enrollment update for your study, A: permission from your program officer, B: the participant-

level data template, C: editing access in the Human Subjects System or D: graph paper. I'll give you a few seconds to answer the poll. All right. Just a few more seconds, and the poll is closed. Let's see what your responses were. All right. So most people got this correct. So the two correct items are the participant-level data template but then also access in the Human Subjects System which is something that I mentioned at the beginning of the presentation. You want to make sure that you have the correct roles to be able to edit information in HSS in order to make your inclusion updates. Sometimes this comes up with PIs as they're beginning to work on their RPPR, and they have research assistants and others that are helping. You need to have access in HSS in order to provide the edits and information that you need.

All right. So let's move on to talk about the clinical trial information that you'll need to provide. So again, first, if you have a clinical trial, you'll need to register the trial in clinicaltrials.gov. Now in this presentation I won't go over the process for that, but there is helpful information on the clinicaltrials.gov website for you to look at if you are the responsible party and will need to be the one who is doing the registration. Here I have a screenshot of the How to Register Your Study page and then also the Protocol Registration and Result System log-in that would be needed to go ahead and log in and register your study.

So with that being said, if you recall, at the beginning of the presentation I mentioned that you can use your Human Subjects System information, particularly your study record data, to provide some of the initial information that you need for your clinicaltrials.gov registration. There are two ways for you to able to do this. So the first way is by going into HSS and, within your line item for any study record that's a clinical trial, there's an Export XML button. When you click on this button, it'll open up an option for you to add your PRS organization name and to create a unique protocol ID for that particular study. Once you do that, you click the Export button, and a file will be downloaded to your computer that you can then use to upload into clinicaltrials.gov to begin your registration. On the other hand, if you're a signing official, there's an additional option for you. So what you can do is access the same way and click on the Export XML button, and when you fill out the initial information at the top of that box that opens up, you can then click on the Upload Directly to clinicaltrials.gov check box. You'll then receive an additional set of fields where you can enter your PRS username and password. You'll have a button there that says Upload to clinicaltrials.gov, and when you hit that, then that'll go ahead and do the upload for you directly into the system. You'll receive a message to let you know if the upload is successful or unsuccessful. If you need more information about this particular process, there is information available in the HSS Online Help for External Users, where there's a specific chapter that walks through this process.

So before we go on, since we're talking about clinical trials, I did want to mention the fields that we have in HSS that also map to clinicaltrials.gov or our shared fields. The fields listed here are specific fields that we, as NIH, check for congruence with the information that's in clinicaltrials.gov. These are fields that we want to make sure are the same so that we can make sure that we have updated information about your study and to confirm that we have the same

information that clinicaltrials.gov does for compliance. Some of these fields include age limits and the recruitment status, also includes the study primary completion date and the enrollment of your first participant, so it's important to remember some of these fields, that you're aware and because sometimes if these fields are not the same, you may receive errors as you are completing or attempting to submit your information in HSS, and I'll talk a little bit more about that in a few more slides.

So now that we have registered our study, let's say, and we are now ready to enter the NCT into the Human Subjects System record that you have for that particular study, so you will enter the NCT in section one, where there's an item specifically for that, a field that you can provide that. Once you enter the NCT, you can use the Populate button that's located next to it to pull the information from clinicaltrials.gov into HSS for the specific fields that I mentioned in the previous slide, and here they are again. So once you click that Populate button, what will happen is the HSS fields that map will populate with the updated information from clinicaltrials.gov. The second thing that you may need to update would be the information in section two. Now, we've talked about how to update your Inclusion Enrollment information, but I want to note that you may also need to update your recruitment status. Now, this is one of the fields that maps to clinicaltrials.gov. So if your study is a clinical trial, this information will populate from clinicaltrials.gov, if you've used the Populate button to refresh the information in HSS with your clinicaltrials.gov information. And then lastly, let's talk about section six which includes the clinical trial milestones. So this entire section is dedicated to kind of key dates and information for your clinical trial. Importantly, there is a date that you provide in your initial application which is the enrollment of first participant date, what you anticipate that to be. Post-submission, that date moves down here to section six, so can be grouped along with all the other dates that you have that are important. So for each date that you have, you can set the date to Anticipated to describe when you anticipate that that particular milestone will be met, and then once it's met, you can update the date with the actual date that it occurred and set that date to Actual. One really important thing to note is that for the enrollment of first participant date and for the study primary completion date, once those dates are set to Actual and that particular change is saved, recipients are not able to make any edits to that date. Part of the reason is for compliance purposes. So if you make an error, if you set the date to Actual accidentally, and you note that it's incorrect, you'll want to check your clinicaltrials.gov information, and if that information is correct in clinicaltrials.gov, you can use the Populate button to refresh HSS and provide the actual information that you want to provide in that field. If not or if, for example, you haven't registered your study yet or your study hasn't begun, and you have to provide an anticipated date instead of an actual date, you'll want to contact your program officer to let them know about the situation, and they can provide additional guidance about what to do next.

So now that we've talked about all of the ways that you edit the information, let's talk about really important thing which is saving your changes, right? So at the bottom of each page in HSS, there are three buttons that will be available to you. There's a Save and Keep Lock button

which you want to use if you're saving the data but continuing to make changes on your records. Then there's also a Save and Release Lock button. So that one you want to use once you've done making all of your changes, and you are getting ready to exit the study, not make any more changes or even close out of the program completely. If you don't release the lock, then if you - Say one of your colleagues is going in to make some other edits. They won't be able to do so because the system will still be locked in on your account. So it's important to release the lock once you're done with the information that you're changing and you've saved those changes. Lastly, there is always going to be a Cancel and Release Lock button. So if you started making changes, and you realize that you've made an error, you can cancel and release the editing block, so you'll no longer be in editing mode. You can also use that if you've already saved information. You enter the page, and you don't need to make any edits. You can hit Cancel and Release Lock to get out of the edit mode that way as well. All right. So we've gone over kind of all of the basic information for editing your information in HSS and providing the updates. So there are some key things that you want to remember that need to be updated. Now of course, first is updating the Inclusion Enrollment information for all studies. Secondly, for clinical trials, you want to remember to register your trial and then provide the NCT in your study record in section one and then use the Populate button to provide updates to your HSS record from clinicaltrials.gov to make sure that we have the correct and most up-to-date information.

So I wanted to talk about a couple of recommendations when it comes to filling out information for your RPPR. The first is that if you have any challenges or significant issues on a particular study, it's important to provide these updates in the narrative of your RPPR. Sometimes we get questions about where that information can be provided in HSS within the study record, and the answer is that the study record generally has the structured fields where you're providing specific information to us, whereas if you want to describe a particular thing about your study and about the progress to NIH and so that your program officer can take a look at it, you'll want to do that in the narrative of your RPPR. The second thing is that when you're making updates for your RPPR, you want to make sure that you go into HSS, complete your updates and then submit your updates before you submit your RPPR. The RPPR image will include your study records, but it will only include the last submitted version of the study records that we have. So if you've made updates in HSS but haven't submitted them, the RPPR will not recognize them and won't include that updated version of your study in your RPPR image, so make sure that you submit your HSS changes first before your RPPR.

So let's talk a little bit about troubleshooting. So I know that often people will encounter warnings and errors in the system, and generally there are questions about what the errors and warnings mean. I want to encourage you to take a look at each of the errors and warnings when you receive them and read the text information that's provided in each of the warnings or errors. Often they'll mention exactly what the problem is with the information that's been provided, and they'll give you some cues about how to address the error or the warning to resolve it. One example would be the clinicaltrials.gov and HSS mismatch error that sometimes

comes up for our users. That particular warning includes the particular study record title and also the field or fields that do not match between the two systems. That way you can go to that study record and take a look directly at just those fields and see where you need to make your changes. Another important thing is to always check submission status when you enter HSS if you would like to make edits. Sometimes users will go into HSS to view information, and then they'll realize there's something that they need to change and then try to make edits without first going back and updating the submission status first. So you'll want to remember to update the submission status first in order to make your edits. Here's a list of some of the common warnings and errors that we receive questions about, and in this table I have a column that has a question about what you might want to look at that might help you resolve that warning or error. So for example, with the first listing, "Inclusion monitoring is required but no IER exists," so the question that you'll want to ask yourself is, "Has an Inclusion Enrollment Report been provided?" If it hasn't, then you'll want to go ahead and provide one. That will address the error that is existing at that point. Another one is "Participant-level data, including age at enrollment, is required." When you see that warning, what you'll want to do is make sure that you've uploaded the participant-level data using the template as required for research that came in on an application January 25th, 2019 or later. There are additional system warnings and errors that you may see. Some of them are related to policy compliance, then others are system validations to make sure that the information that's entered in kind of makes sense overall. So for example, some other policy compliance warnings or errors that you may see have to do with clinicaltrials.gov registration and reporting. As you may know, you must register your clinical trial within 21 days of the enrollment of the first participant and then report results within 12 months of the end of the primary completion date. You may also see policy compliance warnings if there are fields that are required that haven't been completed. Some examples of system validations that you may see instead have to do with, for example, a date that's in the past that you attempt to set as anticipated. Since that date passed, you are unable to set it as an anticipated date. So the system will ask you to either update the date or provide an actual date for that particular field. You may also see system validations for items that are completed for a clinical trial, for example, when your study is not a trial, and the system will ask you to remove that information since it's not required for your study.

So here I have the list of resources that I mentioned earlier that may be helpful to you. They include the ERA HSS Online Help and the HSS Training page that includes videos, the tip sheet that I mentioned, the participant-level data template and other information that will be helpful to you. I also have a direct link to the data tip sheet here along with the RPPR Online Help and the inclusion websites and FAQs, as those will give you more information about the way to provide your Inclusion Enrollment information. All right. So let's take some questions.

Dawn Corbett: Thank you, Rebecca. So we have quite a few questions in the Q&A. Let me start with the first question which is, can you leave sections of the HSS blank if your funding was awarded in 2016, your application was submitted in 2015, prior to the expansion of HSS?

Rebecca Favor: If your application came in - That's a good question. So if your application came in before the implementation of Forms E, so that was later in 2018, then there are fields that you are not required to fill out. However, with that being said, the fields are still there for you to complete, and if you re-compete, then you will then be required to provide that information.

Dawn Corbett: Thanks, Rebecca. The next question Laurie Roman has actually volunteered to answer, so you get a little break. Laurie Roman is from ERA, so we're very fortunate to have her here. The question is, "Is there a guide to HSS like there is for the study record? I recently was told to edit my submitted study record, and now there's a section six in my study record. This is not the pre-award study record guide."

Laurie Roman: There's actually two places to find information. One is online help available through Assist, and I can put that link in the chat or the questions, and also, as Rebecca alluded to, there's a lot of other helpful information for completing the post- submission information in the RPPR manual.

Dawn Corbett: Great. Thank you, Laurie. Okay, the next question is, to confirm, during the RPPR we do not need to update the protocol design or any of the inclusion documents, timeline, study team, et cetera?

Rebecca Favor: Generally speaking, no, you would not have to update this unless you've been asked to provide some additional information by your program officer. There might be a situation in which that may be required, but generally speaking you're required to provide your inclusion information updates at least annually, so that would be in your RPPR.

Dawn Corbett: Great. So this question is along similar lines. What if you don't have any changes or updates to make? Then what do you do?

Rebecca Favor: That's a good question. So if you don't have any updates, if let's say you haven't started enrollment. That's your first RPPR. That's perfectly fine. There's nothing for you to update, so you don't have to do anything.

Dawn Corbett: Okay, great. For the individual-level participant data template, is it possible to save a copy to update and share?

Rebecca Favor: Yes, it is. So when you - The copy that you create to upload to us, of course that file you can keep, and then you can also download a version of what you provided to us from within your IER so that way you can have, you can download a copy from that, and then you can add to your spreadsheet and then upload a new version of it each year.

Dawn Corbett: Okay, great. Another question, if there are no changes in enrollment, I think we did that. If there are no changes in enrollment since the previous RPPR, do we have to upload the participant-level data again? I think you touched on this, but this is specific to the participant-level data.

Rebecca Favor: Sure. The answer is no, so it would be the same. If there are no updates, then you don't have to upload a new participant-level data sheet.

Dawn Corbett: Great. Okay, another question, for a subawardee, who is responsible to report enrollment of participants in clinicaltrials.gov and all related compliance reporting requirements? And let me know if you'd like me to jump in on this one, Rebecca.

Rebecca Favor: Sure. Actually, Dawn, I'll let you take that one.

Dawn Corbett: Okay, great. So if you're a subawardee, NIH, our relationship is with the primary and not with the subawardees, so you would need to coordinate with them. In terms of who's responsible for reporting to clinicaltrials.gov, the responsible party is the person who's responsible for that reporting. However, NIH expects the NIH recipient to coordinate with the responsible party to make sure that happens, so I would talk to the NIH recipient and figure out who's responsible for that. Okay, next question, "There are many times when I update the Inclusion Enrollment Report, and when I save as a PDF draft, the updates do not show. I can see the updates in Assist. However, they do not reflect in the PDF version. Is there something I can do to ensure they match?" Do we know about this situation, or maybe this is news to us?

Rebecca Favor: Yeah, this one is new. Did someone from eRA want to take that?

Adam Levy: Hey, this is Adam, Develop Manager for Assist. I am thinking that this has to do with that age data question that you guys talked to us about, where we're not putting the age data in the image, right, yet, and we're not planning on it. So that's my guess.

Dawn Corbett: So that's a good point, Adam. So right now we don't display the age data to the recipient, so even if you upload, you won't see age. However, you should be able to see the sex or gender and the race and ethnicity of your participants. If you're not, please report that to the help desk, and that will get back to us, and we can investigate if there's some other issue going on. Okay, next question, "Are we not able to just update the cumulative enrollment table manually in the Inclusion Enrollment Report? Do we have to use the template?"

Rebecca Favor: That is a good question. So if your research came in after January 25th, 2019, then yes, you do have to use the template because you're required to provide the age data, and the use of the template is the way that these data can be provided to us. In addition, the participant- level information itself is part of what's required for the 21st Century CARES Act, so we do need all of that information that way.

Dawn Corbett: Okay. This question, Laurie, I may ask your help with, but I will pose this. If the PI delegates an assistant on their RPPR, do they have access to HSS for the grant to update Inclusion Enrollment? So the PI delegates an assistant, I guess. So they've delegated an assistant for their RPPR, and I guess the question is, would that PI delegate have access to HSS to update Inclusion Enrollment?

Laurie Roman: Adam can correct me if I say something heretical, but I do believe we follow the delegation established in commons.

Adam Levy: Correct.

Dawn Corbett: Thank you. And this is similar and a similar question about, how do we apply to get HSS access if we are not the PI, but we're in charge of entering information in clinicaltrials.gov? I would just delineate there, Rebecca, that those are two different sets of permissions. So, Rebecca, perhaps you can speak to how they can get access to HSS or ERA can help with that and then clinicaltrials.gov, which I'm also happy to help address?

Rebecca Favor: Sure. So for HSS access, they would need to talk to their signing official because that individual is the one who assigns the roles. For clinicaltrials.gov, that may also depend on who the individual is in their institution who's responsible for that, and so they would need to talk to them about access.

Dawn Corbett: And you can look up your PRS coordinator on the clinicaltrials.gov website, so that would be separate from HSS access. Okay, great. The next question is, so should we not change either date - and I think they're referring to the enrollment of first participant or primary completion date - to actual until after enrollment is finished?

Rebecca Favor: No, so you'll want to change the dates to reflect when actual enrollment begins. You shouldn't wait until after you've completed your study. The thing that I mentioned about the date locking is just to confirm that the information in there is correct, and that way we know when to anticipate the time by which you should, for example, have registered your clinical trial, but you won't want to wait until after you've completed your study completely to provide the actual dates to us.

Dawn Corbett: Great, and I love how people are helping each other out in the chat.

Rebecca Favor: Yeah.

Dawn Corbett: That's great to see, so keep it up. All right. The next question is, do clinicaltrials.gov and HSS only need to be filled out for NIH-funded studies or all research at U.S. institutions?

Rebecca Favor: So HSS is only used for NIH-funded research, so you wouldn't want to use it for all U.S.-related research. Clinicaltrials.gov, on the other hand, is open to research in general, so that is a different, it's a separate platform that's available as a resource for clinical trial-related information.

Dawn Corbett: Great. The next question is, "If you're completing an RPPR and the enrollment table was completed and final the prior year, how do you complete the human subjects section? If we don't update something, we will receive a warning or error."

Rebecca Favor: Yeah, so that's a good question. The warning that you receive in the RPPR related to not updating your inclusion information is there to remind recipients to update information if it's needed. That particular warning is a warning, so you can see it, and if you don't need to address it, you're still able to go ahead and submit your RPPR because you know that you don't actually need to make any updates.

Dawn Corbett: Okay, we have time for one or two more questions. This one is, "Is there a way to see if a particular grant needs to report age in the Inclusion Enrollment Report? A few of the grants I manage were awarded right around that date you mentioned, so I'm not sure they're applicable to the age-reporting requirement."

Rebecca Favor: That's a good question. So one of the ways that you can take a look at that is the date that the initial application was submitted to see if it falls into that January 25th, 2019 or later application due date phase or time frame. The other thing that you want to do is contact your program officer and ask them to assist you in kind of figuring out if your research or if those projects fall in the Inclusion Across the Lifespan policy.

Dawn Corbett: Okay. The next question is, "It was mentioned that if you have accidentally entered an actual study start date, you can update on clinicaltrials.gov if the correct information is there. However, that would bring all the data back from clinicaltrials.gov. Is that correct?"

Rebecca Favor: That is correct, yes. So it will refresh the information for that date and then the other fields that map.

Dawn Corbett: Okay. So I think we are running short on time. We do have a question about, "Will the presentation be available as a recording?" So, yes, all of this will be available, but I do want to take this opportunity to thank Dr. Favor and all of you for attending the session today. It's been very informative, and the PowerPoint and related resources are located - There's two locations, on the NIH Grants Conference website and inside the Virtual NIH Grants Conference Center. Look for the Human Subjects Research Pre-Con event page. Okay, so we're going to take a few seconds now to bring together all of our HHS and NIH presenters from this 2-day event, and we're going to transition into our extended Q&A, so just give us a few seconds, and we'll shift into our Q&A. Thank you.