Dawn Corbett: Hi, I'm Dawn Corbett, the NIH Inclusion Policy Officer, and today I'm going to talk to you about including diverse populations in NIH-funded clinical research. So, as we get started, I want to first give you a brief history of our NIH inclusion policies. And it really started back in 1986, when NIH established a policy encouraging researchers to include women in studies. This was largely due to concerns that women of childbearing age were being routinely exclused from NIH-funded research. And then in 1993, it became public law that NIH include women in NIH clinical research, and also include members of racial and ethnic minority groups. In 1998, we expanded our inclusion policies by developing the inclusion of children policy in NIH clinical research, which required that children be included in all NIH clinical research studies. And then later, in 2015, we changed the definition of a child ... It had previously been individuals under 21, and we changed that to individuals under 18 to better align with the age of consent to research in the states. In 2016, the 21st Century Cures Act was enacted, and it included a number of provisions and requirements for inclusion. We started implementing those requirements, and in 2017, NIH began to require NIH-defined Phase 3 clinical trials, report the results of analyses by sex, gender, race and ethnicity at clinicaltrials.gov, and in 2019, we implemented the Inclusion Across the Lifespan policy and it became effective for applications submitted [Indistinct] 2019 and later. So now that I've [Indistinct] a little bit about the history of our policy, is I'd like to talk about the current status of these policies. So starting with the NIH policy on the inclusion of women and minorities in NIH research, the current requirements are 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 their exclusion. And the law specifically states that this reason cannot be based on cost, typically reasons of convenience are not considered acceptable reasons for exclusion of these groups. A compelling rationale, then, may be for example, condition does not occur in a specific group, such as the case of prostate cancer in individuals whose sex at birth is female. It would be okay to exclude them from those studies. And we also require that NIH-defined phase III clinical trials be designed to permit analyses by sex or gender, race, and ethnicity. So NIH-defined phase III clinical trials, for those of you that may not be familiar, are a broadly-based perspective studies, and typically the aim of the study if successful may result in a change in the standard of care. We find fairly few, probably about 900 NIH-defined phase III clinical trials but if you fall in that category, be aware that they must be designed to permit these analyses. Now the analyses do not necessarily have to be powered. What we ask is at a minimum that you're able to stratify primary outcome by these variables. So for example, for primary outcome, is the risk ratio. You should provide that risk ratio by sex or gender, and by race and ethnicity. And the intent of this is to inform future studies and the data maybe is for example, a meta-analysis to help in further studies. Now if you're an applicable clinical trial, which are typically FDA-regulated throughout the [Indistinct] studies, and you're also an NIH-defined phase III clinical trial, you then must report the results of those analyses to clinicaltrials.gov. So now I'd like to talk a little bit about the requirements of the Inclusion Across the Lifespan policy. So NIH requires that individuals of all ages be included in NIH human subjects research unless there's scientific or ethical reasons not to do so. As I mentioned previously this is a change from the inclusion of children policy in which children were required to be included but now the NIH requires individuals from all ages be included. And this became effective for applications submitted from the dates on or after January 25, 2019. And for contract solicitations and intramural studies issued after that date. NIH also requires the submission of individual level data on participants' sex or gender, race, ethnicity, and age at enrollment in progress reports. So what are individual level data? Well this shows you an example of what an individual-level participant data may look like, and progress reports are required to submit a CSV file that includes the variables you see here. CSV files are compatible with many statistical programs, including Excel. Essentially provide a spreadsheet with race, ethnicity, sex or gender, age and age unit. We have a template file that you can use to do so. So let's do a quick knowledge check before we move on: True or false? You can type your answer in the chat. Cost is an acceptable reason to exclude women from an NIH clinical research study. Okay. This is false. Hopefully you all got this right. Cost is not an acceptable reason to exclude women from an NIH clinical research study. In fact the law specifically mentions this. That women and minorities must be included in NIH-funded clinical research unless there's a compelling rationale and cost is not an acceptable reason for the exclusion. Okay, so moving on from the requirements, let's talk more about what's required when you're applying for NIH funding. So if you're applying for funding and need to include plans for inclusion of women and minorities, and plans for analyses by sex or gender, race and ethnicity, for NIH-defined phase III clinical trials. And then you also need to provide an inclusion enrollment report, and that inclusion enrollment report will include data on sex or gender, the race and ethnicity of your proposed sample, both planned and actual. And then finally you're wanting some plans for inclusion of individuals across the lifespan. This will be your age limits if applicable, if you don't have age limits that's okay. Just put N/A and a justification for the age range and distribution in study. You'll provide all this information on the PHS Human Subjects and Clinical Trials information form, and this is in section two of the form, study population characteristics. In this section of the form you're going to list your eligibility criteria and you'll provide age limits, including your minimum and maximum age if you have them. Provide plans for inclusion of individuals across the lifespan, plans for inclusion of women and minorities, and then for some additional information related [Indistinct] and then at the end of the section, in 2.9, you provide your inclusion enrollment report. So it's talk a little bit more about the inclusion enrollment report. This is the example of an inclusion enrollment report. This is the first section, which includes text fields. You'll need to provide an inclusion enrollment report title. This was [Indistinct] forms have that each enrollment report must have a unique title and then you indicate whether or not you're using an existing data set for resource because any age [Indistinct] your data and aggregates them in the reports to Congress each year. It's important to us that you answer this question correctly so that our data aren't skewed. And you can find more information on your website about existing data set of resource, but in a nutshell, for example, if you're using existing samples, and you know what that looked like at the time of application, then you indicate that you would need an existing data set of resource. Yes. We'll also provide you with enrollment location, type, can optionally provide the countries in which participants will be enrolled. One note: If you are including both US and non-US participants you need to provide separate forms for US and non-US participants [Indistinct] separately. And then you can provide your enrollment location and comments, optionally. So this is what the inclusion enrollment reports look like. They're both planned and actual reports, typically at the time of application we provide a planned report. But if you're using an existing data set or resource you may just provide an actual report. You may include a table with distribution, by sex or gender, by race, and by ethnicity. Once you submit that information to us it will then go to peer review, and peer review will consider the information. Peer review will also assign codes that indicate whether or not they find inclusion to be acceptable or unacceptable by sex or gender, by race, ethnicity, and by age. Which you see in this example here, there are codes, gender minority and age, the number is just listed distribution of the subjects. And then the A or the U code indicates whether or not peer review found it to be acceptable or unacceptable. So in this case here, they found the gender and race, ethnicity distribution to be acceptable but they found the age to be unacceptable because children were not included. If any of the codes are U which means peer review found any of these inclusions to be unacceptable, your study cannot be funded until this is resolved and so [Indistinct] peer review your study may be funded and will need to provide some additional information. So now that we talked about what's required, let's talk about how do we make a good inclusion plan? One thing to take a look at as you're making an inclusion plan are guidelines for review and inclusion on the basis of sex or gender, race, ethnicity, and age. This is available on our website and you can see the peer review it uses as guidance to determine if the [Indistinct] acceptable. And the bottom line is [Indistinct] is it complete? Did you provide the required information? Did you discuss the inclusion of women, racial and ethnic minorities, and individuals across the lifespan, and did you provide all the correct tables and information? And then you're going to look at if inclusion is scientifically appropriate. So this is a little bit harder. Sometimes people ask me, "well what's the formula? What's the percentage that I need?" And the short answer is, there isn't a specific percentage that we can give you. We're going to look at inclusion in the context of the scientific question and determine what inclusion is appropriate in the context of your study. So we'll be looking at things like will your research be generalizable, if [Indistinct] codes to subgroup analyses. Are those [Indistinct] empowered, and so on. And then finally, we'll also look at whether the inclusion plan is realistic. So you may provide a beautiful inclusion plan but you haven't given us enough information to convince us that you'll actually be able to complete this plan. For example, you may live in an area with very low racial and ethnic minority populations, and you have proposed a plan, which indicates a diverse sample. You haven't told us how you're actually going to recruit these folks. So it is important to provide enough information so that we understand that you can execute the plan and that's why average plans a part of the inclusion plans that we'll be submitting. I want to share with you some feedback we received at a September 2020 workshop we had on Inclusion Across the Lifespan II. So the purpose of this workshop was to get some evidence-based practical advice on implementing NIH inclusion policies. Specifically inclusion across the lifespan. But we also discussed inclusion of individuals by sex or gender, and race and ethnicity. And I think some of the recurrent themes that we discussed will help as you think about inclusion. So some of the discussion mentioned the importance of selecting trial outcomes that reflect participant concerns. So sometimes we see studies struggle with inclusion because the scientific question that they're asking or the outcomes that they're looking at, may not be as important to the participants and thus they may have struggled to find people to be in the study. For instance, if you're working with older populations, maybe mortality is not the primary outcome of interest. Maybe it's quality of life. Maybe it's functioning. So it's important to engage with participants to understand what comes about comes according to them. Also one of the things ... Just on the use of unnecessary inclusion/exclusion criteria. So this is a big one. So certainly if you specifically exclude women, [Indistinct] racial and minority groups, and individuals of any age group, those need to be justified. But you also need to make sure that the rest of your inclusion or exclusion criteria are appropriately justified and necessary. Often inclusion and exclusion criteria may disproportionately affect certain groups. For example, if you exclude people with hypertension, you're disproportionately excluding older individuals or may be disproportionately excluding individuals of certain racial and ethnic minority groups. That doesn't mean that you can't exclude people with hypertension but it's certainly inappropriate in some cases. But it should be justified. And you also want to look at your inclusion and exclusion criteria as you move through the phases of your trial. And make sure that they're all still necessary. Another thing was adequately weighing risks of excluding groups like pregnant women and children with that of their participation. So this is something that I'll leave for the investigator and study team to consider but also for [Indistinct] when we're looking at participation of groups with additional protections, we want to make sure that part of that risk assessment also involves what happens if they don't participate. And I think that the current situation with COVID-19 really shows us what happens if we don't have willing participation of groups like pregnant women and children. May be completely acceptable but there are public health consequences to them not participating and so we have to make sure that those assessments and keep all that information. Another thing was minimizing participant and caregiver burden. And so this is really good advice to help you recruit in general but certainly thinking about this in terms of racial and ethnic minority groups, and so when you have complex medication regimes, when you have multiple study visits, multiple procedures. This makes participation harder. And it often makes it disproportionately harder for certain groups. You also want to think about things like transportation, child care, etc. How can you minimize the burden to participants and to the caregivers on the study? It's also important to consider the diversity of individuals within a given group, so when you talk about specification, we talk about racial, and ethnic minority groups or sex and gender groups. There's a lot of diversity within those groups, such as size, comorbidities, diet, cognitive status. These are important things to think about as you're designing your study, think about how you're going to accommodate a truly diverse populations. And then, lastly, one of my favorites, is regularly assessing recruitment and retention, and make modifications as needed. This is really such an important part of a successful inclusion plan. Is checking in and seeing how you're doing periodically. Are you having team meetings on a regular basis? We hope your progress report isn't the first time you're looking at recruitment and retention in terms of deciding if modifications are needed. Modifications early on are off limits the fact that I was encouraging her to take a look at recruitment and retention early and often. Some other things to consider: Things to think about are the demographics of the source population. This sounds quite simple, but often this is not provided in an application. And sometimes, people fail to think about this. But what does your source population look like? What kind of data do you have? Are you recruiting from an institutions clinic. What are the demographics for the patients who come through that clinic? How many people come to the clinic. How many are likely to be eligible for your study according to the demographics of the individuals who are likely to participate in your study. What does that all look like? So this is all making sure you have enough data, just like any other part of your application. To support your inclusion plan. It gets back to that realistic part we talked about earlier. Think about family, community involvement. So we talked about minimizing burden, but also thinking about how will families be involved in your study? How will you communicate with families? How will you communicate with the community you have? For example, a community advisory board that you'll be working with? Language and participant communication is important, so do you have translation services and what languages will you provide consent forms and what kind of supports are in place at your institution. What kind of staff expertise do you have and [Indistinct] include many groups, you want to make sure you have the expertise to work with the groups as well, so if you're a pediatrician and you're going to be working with older adults, do you have the expertise to do that. Do you need to get that expertise. Will you be bringing people onto your study team. Will you be hiring consultants, so think about what kind of expertise that you need to work with populations [Indistinct] and how you'll get that. And then finally, budget. Sometimes, it may cost more money to include certain groups. You may need to provide additional services. Sometimes appointments may take a little bit more time. For example, if you're working with individuals with cognitive impairment, you may need a little bit more time to explain things. May need to take more time for consent. Make sure your budget allows for that and I encourage you [Indistinct] with your program officer on that. Okay. So, now that we've talked about what makes an inclusion plan and things you can consider, I'm going to put you in a position of an NIH peer reviewer. We're going to look at some case studies and you're going to tell me whether you think this is a good inclusion plan or not. If it's a good inclusion plan we'll call it thumbs up. If it's not a good inclusion plan, thumbs down. And you can put your answer in the chat. So the first case study: "A researcher proposes a study to determine the efficacy of a novel treatment for prostate cancer. The study excludes individuals whose sex at birth is female." What do we think of this? Thumbs up, or thumbs down? I'll give you a minute to consider. Okay. Well hopefully, this one wasn't too hard for you. I mentioned this earlier. So this is a thumbs up. In this case, the condition does not occur in the excluded group of females, those whose sex at birth is female. So it's okay to exclude individuals from this study. I'll give it a thumbs up. Now let's move on to the next case study. So case study two: "A researcher proposes a study to examine use of a smartphone app to improve glycemic control in diabetic individuals. The study excludes individuals who do not speak English, because the consent form is available only in English." What do you think? Thumbs up, or thumbs down? Put your answer in the chat. Okay? I gave this one a thumbs down. Why did I give it a thumbs down? I gave it a thumbs down because they're excluding people who do not speak English, which disproportionately affects racial and ethnic minority populations. Even though they didn't specifically exclude racial and ethnic minority populations from the study, the likely effect is they will have fewer racial and ethnic minority individuals because of this exclusion criteria. And they haven't given me any justification. Why can't they translate the consent form? Why don't they have any supports in place for this? So I would need more information to consider this acceptable. Until I have that information, I'm calling this unacceptable. All right, let's do our last case study. In this case study, "a researcher proposes a study in individuals 18 to 60. The study indicates children are excluded because the legal age to consent to research is 18 in the state where the research will be conducted. Individuals over 60 will be excluded because of the likelihood of comorbidities in this group." What do you think about this one? Put your answer in the chat. Okay. I give this one a thumbs down. For a couple of reasons. So why is this a thumbs down? So this study excludes individuals under 18, and it says because the legal age of consent is 18 in their state. But there are generally ways to include children ... Parental consent, or assent in many cases. And so I would expect the researcher to give me more information about why they can't do those things? Why is that not practical or desired here before I would call that acceptable. And then they're excluding individuals over 60, because of a likelihood of comorbidities in this group. In general, it's better to exclude people with certain comorbidities if needed rather than excluding people based on the likelihood of those comorbidities, so, for example, if they're concerned about diabetes, they can [Indistinct] people with diabetes. Although they also want to make sure that those inclusion and exclusion criteria are really necessary. In this little bit of information I have here, I don't know whether they need to exclude people with comorbidities or not. But if they do that should be explained in the inclusion plan. All right, great job with the case studies. Let's move on to Just-in-Time requirements. So as your study goes through peer review, if you need a certain percentage threshold, you will receive a Just-in-Time letter. At that time you'll be working with institute or center staff to resolve unacceptable inclusion concerns, if there are any. So if you saw any of those new codes, this would be the time when you'd be working with the I/C staff to resolve those. And also if you need any corrections of the programmatic adjustments or the peer review has suggested certain adjustments to your study, you may provide updated information [Indistinct] or corrections at this time. And then, if you're funded, congratulations on getting funded first of all. There'll be a few things that you'll provide afterwards in your progress reports. So you'll be providing actual inclusion and enrollment data in progress reports. Each year you'll provide us an update on the individuals who are included in your study. And that information will be cumulative over time. And if you're conducting an NIH-defined phase III clinical trial, you do need to give us an update on the progress of your analyses by sex or gender, race and ethnicity. Now, if you're early in your trial, these analyses may be in progress. And that's fine but do make sure you leave a statement in your progress report indicating that. And then as a reminder, as we mentioned earlier if you're doing this [Indistinct] FDA-regulated drug and vice studies that are also NIH-defined phase III clinical trials, you will need to report results of analyses by sex or gender, race and ethnicity at clinicaltrials.gov within one year of your primary completion date, and that would be submitted along with the rest of your information to clinicaltrials.gov, on your results. And then if you were doing any delayed onset studies and these are studies that you can't describe at the time of application. It may be for example, [Indistinct] before you fully developed that protocol so if you have any of those that you didn't provide clinical information for at the time of application that you'll be working on, you will provide a full PHS Human Subjects and Clinical Trials information form for the study. And make sure you're in touch with a program officer as you may need prior approval if we start that study. So when you're submitting progress reports, and you provide us those updates on enrollment progress, you'll be using our human subjects system. You can see the screen here for submitting this information where you submit your actual data. If you submitted your competing application January 25, 2019, or later, you'll actually need to be providing that spreadsheet that I showed you. And you can see her on the screen. You can download the template for that spreadsheet from the Human Subjects system and then upload it into the system. That will populate this table for you. And we have a lot of resources on using the Human Subjects System at our HHS training site, which is in the ERA help and tutorials page. Including a video that goes through the process of how to edit studies and how to submit them to NIH. Okay, let's do one last knowledge check. This is a true or false question. "If funded, NIH recipients will need to provide data on participant race, ethnicity, sex or gender, and date of birth." True or false? You can put your answer in the chat. Okay. I'm going to admit this was a bit of a trick question but for those of you who are listening carefully you'll know this is false. You do need to provide data on participant race, ethnicity, sex or gender, but you do not need to provide data on date of birth. We actually correct age at enrollment rather than date of birth for participant privacy concerns. So that's all that I have for you today. I really enjoyed discussing with you and I hope you all provide any questions. They're in the chat. We also have a number of resources on inclusion of women and minorities and inclusion across the lifespan. And you can reach me at the e-mail address on the screen, inclusion.mail.nih.gov. Thank you very much.

Lyndi Lahl: Great, thank you, Dawn. So there are some questions in the Q and A portion. I encourage people to continue to send those in if you have other questions. So the first question I want to pose is, do you have suggestions for recruiting and retaining racial and ethnic minorities in research?

Dawn Corbett: Sure, and so I covered some of this in the presentation, things to think about as you're creating your inclusion plan. And I think one of the most important things is to engage the potential participants from the very beginning in your study design. Are you answering ... Are you asking the right questions? And make sure you're meeting the needs of those populations. The other thing to think about is how are you communicating with people both throughout the study and also after the study? The main reason that people participate in research is altruism. They want to do something good, in a way that you go, and you go out to vote, because you want to do something good. You want to participate in society. And it's really important to let people know how they contributed, to share your results of research with your participants and so in terms of specific strategies there are a number of tool kits out there. We have some resources on our website on which we can give you some specific tips for working with certain populations. I can't tell you one thing that will work with all populations. Other than, really, to engage the participants throughout the process.

Lyndi Lahl: Great, thank you. Somebody would like you to define inclusion across the lifespan in research. They feel that it's kind of confusing.

Dawn Corbett: Sure. So what we mean by inclusion across the lifespan is inclusion of individuals of all ages. Sometimes we get questions whether we're talking about development. Not necessarily, but the bottom line is that if you are excluding any age groups either it should be justified and your overall inclusion based on age should be age-appropriate for each study.

Lyndi Lahl: Okay, great. So, somebody has posed the question, why not include sexual orientation, which is another important demographic variable, in these guidelines?

Dawn Corbett: That's a great question and so I want to state that there are a number of health-disparity populations other than those that I've talked about today. NIH recognizes other populations as health-disparity populations including sexual and gender minorities, individuals from disadvantaged socioeconomic backgrounds. And others. This policy is specific to a Congressional mandate for the inclusion of women and racial and ethnic minority groups, which is what I'm addressing here today. But certainly NIH's position is that the default should be inclusion. And we should try to be ... Do research that's as inclusive as possible. And certainly, when we're thinking about the questions that we're asking want to be answering those questions for as many people as possible, and not excluding certain groups.

Lyndi Lahl: Great, thank you. So, somebody has written that exclusion based on language is problematic for a number of reasons. Can you discuss the acceptability of inclusion criteria that is ability to speak, read, and write in English? I think we probably have all seen that.

Dawn Corbett: Yeah, and I agree. I think this is something we talked about a lot. When is it appropriate to exclude people who speak languages other than English, or do not speak English. I think it's something that you have to consider very carefully and I think this is something that we do only when we have to. So in general our expectation is always that you make accommodations, so that your research is as inclusive as possible. I think there's another question that we received is sometimes the instruments are not available in those languages. And that's an issue. I think we, as a research community, need to do a better job in making sure that we have valid instruments that we can use in a number of communities. So while we recognize the challenges, we do encourage you to be as inclusive as possible, and I think if you have questions about your specific research, talking with your program officer is a good place to start. About how you can make your research more inclusive.

Lyndi Lahl: Great, thank you. Another question about subpopulations. And the question is, how are subpopulations captured when reporting inclusion data? They give an example: someone from Haiti is different than someone who's African American. Is there a separate section or form to capture this difference?

Dawn Corbett: This is a good question. I'm glad that you asked this. And one thing that I'd like to make clear is that the categories that you use for reporting to NIH are the minimum categories we require for reporting purposes to us. This should not limit you in any way in terms of the information that you collect from your participants so we encourage you to collect information on subpopulations both racial and ethnic minorities, and gender or sex subpopulations, as well. One question that sometimes we get is can we collect information on non-binary populations. Of course you can. We would encourage you to collect information that's appropriate for the group that you're working on and for the participants for which you're working. And in the context of your scientific question.

Lyndi Lahl: Very good. So somebody has posed a question. If they're doing research outside the US, and ethnicity is not typically captured, then what should they do?

Dawn Corbett: Great, so we understand that if you're doing research outside the US, the categories that we give you may not be categories with which the population with which you're working identify. You can use culturally-sensitive terms, culturally-sensitive instruments for collecting data on risk and ethnicity. You don't have to use the same terms and the same language that we use. The only thing that we do ask is that you can aggregate those into the categories that are provided. If you look at the definitions of race and ethnicity, that can help. The definitions are often based on continent of origin with lots of caveats and exclusions to that, but that's one place to start, and then you can use the terms that are appropriate for the population with which you're working.

Lyndi Lahl: Thank you. So another question: What, if anything, is done after NIH realizes that certain minorities have been excluded from an NIH-funded study?

Dawn Corbett: So this is a good question. So the first step is going to be peer review. So if your inclusion plan excludes certain groups, and that's not justified in your application, then peer review would mark that as unacceptable. And then that study cannot be funded until any concerns are resolved. And so typically that involves working with a program officer on that inclusion plan. To make it acceptable. And in the case where a group may be excluded, after it may be proposed or inclusion plan and included these populations, but you actually do not enroll those populations. That's something that we would deal with in program monitoring, so as I mentioned in the presentation every year you have to submit a progress report. And so if your progress report does not show adequate program in terms of enrollment of either women, or racial and ethnic minority populations, your program officer would not be able to sign off on that award until they were confident that you were going to enroll the populations that were needed for the study. So again your program officer would likely reach out to you to resolve that situation.

Lyndi Lahl: Okay. Somebody has asked about obtaining slides and watching the presentation, probably for some of their colleagues, if they weren't able to attend the live session.

Dawn Corbett: Yes. So, um, we do have slides available. If you go into where you join the session there is a link to the slides there, right under the session descriptor so you can see those. And the video will be available. Within 48 hours, on the presentation.

Lyndi Lahl: Great. We are getting close to the end if anybody has any other questions that they would like to submit, we have time for maybe one or two more. Okay. This may be the last one. Dawn, what percentage likelihood is acceptable to exclude a certain age group? So, for instance, for stroke, there are pediatric cases as well, but it's a very low percentage, maybe less than 5 percent of overall cases.

Dawn Corbett: I think this question may be what I was talking about in regards to comorbidities and so, one example that we see is hypertension, which a number of individuals and I don't know the exact percentage over 65 have hypertension. Sometimes we'll see studies that just exclude everyone over 65, because they don't want to do the screening for hypertension or they don't want to have a number of potential participants come in, and then they're not going to be eligible. And so we would discourage that. We would say your inclusion and exclusion criteria should only be those that are necessary. Especially when it comes to these populations that we're talking about here, and these policies. If it's going to disproportionately impact anyone based on age, or sex or gender, race, ethnicity, then we need to be very careful about that. So if you really do need to exclude people with hypertension because of safety concerns then what we would say is exclude people with hypertension. Don't exclude everyone who may be likely to have hypertension.

Lyndi Lahl: Okay, and I actually found there's one more short question. I think this really will be the last one. Can you recap what the Excel sheet was for?

Dawn Corbett: Sure, and so in terms of the Excel sheet, this is for the individual level data, if you have had an NIH grant, you may have submitted tables to us. With sex or gender, race, and ethnicity of the participants. With the inclusion across the lifespan policy we now require that information be provided for each participant. So you send an Excel spreadsheet that indicates the sex or gender, the race, and the ethnicity, and now, the age at enrollment, for each participant and you'll upload that into our systems with each progress report.

Lyndi Lahl: Great. I actually found one more question, if you don't mind answering.

Dawn Corbett: Sure, sure.

Lyndi Lahl: How should the researchers deal with multiracial participants, which seems to be a very common occurrence.

Dawn Corbett: Yes, so we do have a category more than one race, and so you can indicate how many participants you expect to identify as more than one race, on the planned enrollment form. You can also report that when you report your actual enrollment. How you ask the question is up to you. Sometimes people will list for example all the racial categories and then you can select all that apply. Sometimes people have a box with more than one race. Again exactly how you ... The categories that you use are really up to you, as long as you can aggregate them and send those to us.

Lyndi Lahl: Great, thank you. I think that we're going to have to wrap up now. Thank you, Dawn, very much for this informative session. If you glance at the chat, you'll see a lot of very positive feedback, so that's always nice to hear. Thank you. If you do have any additional questions, know that we have resources available on the website. If you go to the DHSR booth, we have some links to resources there. And you can always find contact information on the help section of the NIH.gov website, grants.nih.gov. I also want to mention that your feedback is very important. There is a session feedback button located on the description and presenters' section in the auditorium list of sections, so when you're done, we would appreciate the feedback, the overall survey form, and that's it. Thank you very much for your time and attention. I hope you have a great rest of your day.