Transcript: NOFO Informational Meeting - Component A

Understanding and Promoting Resources and Opportunities for People with Autism and Fragile X Syndrome and Their Families Across the Lifespan

NOFO DD26-0025

Reader note: This is a cleaned AI generated transcript intended for readability, not a certified verbatim transcript.

OPENING, NOFO SUMMARY, AWARD, AND ELIGIBILITY INFORMATION

A version of the NOFO that's available on Grants.gov. And we've also included some page numbers from the as that you can reference throughout the call. Please mute your phone lines and speakers and submit any questions that you have in the chat box. We will respond to them at the end of the presentation and also post the FAQs on the NOFO web page after the call. Again, welcome to the informational call for potential applicants for NOFO DD26-0025. Understanding resources and opportunities for people with Autism and Fragile X syndrome and their families across the span. We're dividing today's call into different parts. The first hour from eleven to twelve o'clock, will focus on component A, and the second hour, 12:00 to 1:00 p.m. will focus on components B and C.

Here's the agenda for our call this morning. We'll have multiple members of our team presenting different parts of the NOFO. I'll begin with the summary of the NOFO and award and eligibility information. This NOFO aims to better understand the resources and opportunities that people with autism or fragile X syndrome and their families need in areas including education, transition into young adulthood, and services and supports. The goal is to reduce morbidity and mortality, as well as improve long term outcomes, including health and well-being. CDC will fund three components under this NOFO. We'll spend the first hour of the call discussing component A or the survey to promote resources and opportunities for autistic teens and young adults, or SPROUT for short.

This project is a five-year cooperative agreement broken into five 12-month periods for component A, we will fund up to seven awards. The amount for budget period will be based

on the number of participants that the awardee will be recruiting. Applicants may apply for the components for any of the components for which they have the capacity.

I will now turn it over to Lisa Wiggins to provide a brief background and history of SEED research.

BACKGROUND AND HISTORY OF SEED RESEARCH

Good morning, everybody, and welcome to the call. I'm going to give you a brief background of autism and some of our previous activities, pertaining to autism. So as most of you probably know, autism is a neurodevelopmental disorder. It is defined by deficits in social communication and interaction and restricted repetitive patterns of behaviors and interests. Traits of autism generally appear in the first few years of life, although they may not become fully manifest until social demands exceed individual capacity. Autism is associated with a variety of different co-occurring conditions like attention deficit hyperactivity disorder, anxiety, depression, sleep disorder, and intellectual disability.

These co-occurring conditions can exacerbate autistic traits and create complex phenotypes defined by a wide range of challenges, skills and abilities. In 2022, the CDC estimated that 1 in 31 children aged eight years had an autism diagnosis or special education classification documented in their health or education records. The study to explore early development were. SEED was launched in 2006 to better understand the risk factors associated with autism and how behaviors manifest in the first few years of life. SEED is a multi-phase, multi-site study of two to five-year old children with and without autism. It is currently the largest U.S. study of preschool aged children with autism, and has enrolled over 8,000 children, with over 2,000 children who have autism or another developmental disability.

We have published over one hundred papers SEED papers thus far, including analyses of potential risk factors and phenotypic characteristics, um as well as co-occurring conditions. Next slide please. Autism research beyond early childhood has consistently received the least amount of federal funding, representing only 4% of federal dollars

allocated to autism research. To address the need for more life span research, the SEED cohorts were surveyed between 2018 and 2021, and then again in 2022 and 2026. And the SEED teen and SEED follow up surveys. Although both surveys helped identify the health care experiences and needs among adolescents with autism, gaps still remain and how to best support people with autism and their families as they grow older.

For instance, although SEED, teen and SEED follow up surveys both identified problems with service access like issues related to cost. They did not probe how systemic interventions could help lessen these problems. Also, both of the surveys were over one hour long, and while the surveys collected information on a wealth of exposures and outcomes, participants recommended shortening future surveys to better address areas identified by the autistic community as important and publishing results faster to inform public health action. And now I will turn it over to Angela Thompson. Paul.

COMPONENT A: SPROUT PURPOSE, STRATEGY, DATA COLLECTION, AND DATA MANAGEMENT

Thanks, Lisa. One, two and three. Including, participants who have autism spectrum disorder, developmental disorders, and population comparison group participants who will be approximately ten to twenty eight years of age when the project is awarded. Data will be collected in two survey waves, intending to collect and disseminate data in a more timely manner. Wave one survey will collect data on services and support needs, daily living skills and co-occurring conditions. Wave two survey is expected to collect data on educational, transitional, social and or vocational needs and experiences of the young people in the study. Next slide please. All applicants must demonstrate in their applications that they have access.

Phases one, two or three. As such, applicants must be either one of the original SEED sites that collected data from children ages two to five-years of age and their parents, or document collaborative agreements to work with one or more of the original entities. The original entities are listed here on the slide and they're found in the NOFO slide, please. There are three strategies and eight activities identified for SPROUT strategy. One includes collecting and managing timely, unique data on people who participated in SEED one

through three. The activities include recruiting and collecting eligible participants, um collecting survey data and issuing participant incentives, managing the collected data, and cleaning and sharing the de-identified data back with CDC.

More will be shared about this process in following slides. Strategy two will focus on translating data into high quality public health products. Following each wave of data collection, CDC will lead publication of an all-site data brief, on which sites will be expected to collaborate. Each site will also develop their own site-specific data brief as well as developing and disseminating two additional public health products. These could be peer reviewed publications, or they could be products such as easy to read, summaries of findings, updates to cite websites or infographics. And strategy three is to disseminate public health information garnered from SPROUT, as shown here.

It, will include working with community partners to help disseminate the data briefs. Um, and various methods may be used such as health fairs, partner newsletters and things like that. Right. Awardees are expected to conduct all recruitment, enrollment, survey, administration and data collection activities in the time frame specified by CDC. Pool from caregivers in their adolescent or young adults. Uh who from all samples who previously completed seeds one, two or three awardees will find and verify contact information for eligible participants. Send survey invitations and conduct enrollment calls to those who received an invitation. There will be two ways of data collection yielding data from four surveys.

Total awardees are expected to install and maintain a CDC developed REDCap database to ensure uniform data collection across sites. This includes providing IT infrastructure, updating local REDCap systems, and ensuring effective user operation of the system. The wave one survey will be programmed within REDCap and administered using a mobile friendly format to facilitate participant access and ease of completion. The Caregiver and Young Adult survey should each take no more than 20 to 30 minutes to complete. Participant incentives should be issued and tracked upon completion of surveys. Applicants need to submit a data management plan with their application.

The data management plan should be updated as needed and resubmitted to CDC for annual review. Awardees will be required to host and use R software, a free and open

source software for data management. Provide R training for staff members if needed and ensure local expertise for troubleshooting. Data access should be restricted to only investigators affiliated with SPROUT and controlled as appropriate. Survey data should be cleaned in R using CDC developed programs to ensure all personally identifiable information is removed. Awardees will work with CDC to facilitate data upload and exchange a subset of the finalized pool data. Data may be made available for public use, consistent with CDC policies and applicable law.

PERFORMANCE MEASURES FOR STRATEGIES 1, 2, AND 3

Turning it over to Patrick.

All right. Thanks, Katie. So for these slides, I'll go over briefly some of the performance measures associated with each of the activities under strategies one, two and three. So for strategy one, um for the first activity of recruiting and enrolling eligible SPROUT participants, um the first two performance measures which will ask for information, once beginning of year one, is to report the criteria used to determine eligibility and the total number of eligible participants in your site, and to report the steps that you're taking to contact those eligible for SPROUT. Um, the second two performance measures under this activity are to report the number of, of those eligible that were invited, contacted, enrolled, on a monthly basis and have at least one site representative attend all of the, all-site calls that we anticipate will be occurring on a monthly basis as well.

Next slide.

For activity two, collection of survey data, we have two performance measures, which include reporting of those eligible who completed the survey, and any challenges or barriers that were encountered when collecting the survey data and any proposed actions to overcome those challenges. Both of those are expected to be reported on a monthly basis beginning in year one, quarter three for activity three in the management of data. Um, the expectation for the performance measures that are complete, the confidentiality training. So that applies to all local investigators um and occurring on an annual basis. And

then also again ensuring there is one representative that attends all SPROUT project coordination and data management calls on a monthly basis.

And the final activity under strategy one is the cleaning, cleaning and sharing of data. the two performance measures under this activity include upload and transfer of de-identified data files via the SFTP to CDC on a monthly basis, and then a completion of the data cleaning procedures and submitting the final data to CDC, which we anticipate happening. Twice throughout the funding period, first and year, beginning of year three. In the second. The beginning of year five.

The required performance measures for strategy two. For the first activity, the all-site data brief is simply just to ensure you have a site representative attending all the calls related to the all Site brief. The second activity for the site-specific briefs is participating in site-specific calls with CDC as needed. And then finally, the development of two public health products.

The required measures are to submit two LOIs for other health products that do not overlap with the all-site or site-specific briefs. So these would be distinct from those briefs. And then also to submit the final health product from that LOI within eighteen months of approval, to CDC.

And finally for strategy three, which is a dissemination of the data briefs. Um, the first performance measure is just providing evidence of collaboration with at least two community partners that will help in dissemination and release of the data briefs. Second is to report the number and type of dissemination methods identified by the site and community partners, and the potential, the reach potential of each of these methods. Um, and we expect that information to be provided twice at the beginning of year two and beginning of year four. And then final two, performance measures. Um, describe more of a report summary that includes elements or information about the number of dissemination activities and then events or activities conducted, any barriers or challenges that were encountered and the reach metrics for each dissemination activity.

Um, and also providing any details on the attempts to strengthen partnerships that include number of partners, reach and number of data briefs disseminated. Etc.

APPLICATION SUBMISSION, REVIEW, SELECTION, AND KEY DATES

I will now focus on submission procedures for the application.

A letter of intent from potential potential applicants is requested, but optional. This allows CDC to estimate the number of applications and plan for the review. You can send the LOI via email to me at CDC@cdc.gov with the following information. The NOFO number and title, your organization's name and address, contact name, phone number and email address, and the components for which you are planning to apply.

These are the different parts of the application that you will need to submit for the project narrative. There is a limit of 20 pages, including the work plan, and it should include the background and approach evaluation and performance measurement plan and organizational capacity. You will also need to submit a budget narrative which is not scored, and you may also submit attachments as needed.

The budget narrative supports information provided in standard form 424A and explains and justifies the costs in your budget and includes all of the categories listed here.

Here are some of the budget items specific to component A. You can also find these details in the NOFO.

I will now go over the review and selection process.

Once your application is submitted by the deadline of June 15, the office of Grant services will do an initial review of all applications for eligibility and completeness.

Applications that are not responsive will not advance to the next phase of review. A panel outside of our division, the Division of Human Development and Disability, will review applications using the scoring criteria outlined in the NOFO. A review is also conducted to review the risk that recipients will not manage federal funds prudently. An objective panel will review each application and assign points for each section. The background and approach are worth 45 points total. The Evaluation and Performance Measurement Measurement plan is worth 20 points total, and the organizational capacity is worth 35 points total. The next few slides provide details about how the points will be assigned within each section.

For the sake of time, I won't go through these slides in detail, but you can find all of this information detailed in the NOFO.

Applications will be funded in in order by the rank that the review panel determines when making funding decisions. We will consider merit review results. Although these are key in making decisions, these are not the only factor. CDC may fund applications out of order to ensure demographic and geographic representativeness, and also the recipients ability to access participant contact information. CDC may fund applications in whole or in part. They may fund applications at a lower amount than requested, or CDC may approve, but not fund one or more of the components, which could be funded in the next fiscal year. The number of awards is subject to available funds and agency and program priorities.

If awarded, CDC will email a Notice of Award to your authorized official. We will also notify you if your application is found not responsive or unsuccessful.

Here are the key dates for the NOFO. The optional letter of intent is due June 1.

Applications are due before midnight on June 15. The tentative date for awards to be issued is August 31, and the project start estimate is estimated for September 30.

Here are the contacts for the NOFO. I will serve as the project officer, and Robin Bryant will serve as the Grants Management Officer for this project. If you have any questions about submission, please contact the Grants.gov help Desk.

QUESTIONS AND ANSWERS

We will now spend the rest of the hour addressing any questions you have about component A.

Please continue to submit questions in the chat box or use the Raise Your Hand feature in Teams.

All questions after today's Informational calls should be sent to the SPROUT@cdc.gov mailbox by June 9. All. All of the questions that we received for this NOFO will be answered and posted on the website listed here after the call. The website will continue to be updated as we receive questions throughout this from the SPROUT mailbox.

All right, we will turn it over to you all to ask any questions that you have.

Thank you for joining us today. And we have one hand raised and one hand one question in the chat box.

Carolyn, go ahead with your question, please.

Thank you. thanks for this summary. Actually, it answered some of the questions I had, which was very helpful. Um, one question which wasn't quite clear to me, and I just want to confirm is do we start fresh with each of the two surveys, or is the second survey only administered to people who completed the first survey, and then do the percentages, then follow from that. Thanks for your question, Carolyn. So ideally, the we would have

participants answer both surveys, but participants who don't answer survey one would still be eligible for survey two.

Thank you.

The first question in the chat is are all groups ASD, DD, and POP eligible to participate in sprint? The answer is yes. All. All previous participants who were included in SEED one, two, and three are eligible to participate in SPROUT.

The second question in the chat is will there be a single IRB or should each site plan to use a local IRB? Um, I'll take that one. So because CDC determined this, project to be nonresearch, it will not be going through species IRB. Um, that does not mean that each individual site, it's their institution requires it, they can get a research determination there. And if it is determined to be researched, they will go through their own IRB. And that question was from, um Chris Acosta. And she's just raised her hand. So

Chris, go ahead if that's a follow on question.

Thank you. It is. And I have some others, but I'll wait on the others. So then would that be considered an allowable, um expense in the budget. The IRB. Correct. Therapy usually happens I We.

Chris. We will research that and get back to you. Um, I'm not okay with the associated expenses are but but we'll on that. Yeah. And, and I only say that because the, you know, it has impacts on our budget because this is not considered research. The IDC rate for our institution does not include research or costs, let's say related to IRB or other services that would be provided through a more traditional research based IDC, which does recoup and recover those costs as part of it. Okay.

Thank you for letting us know. We'll definitely follow up on that and get back to you. Okay. The next I don't see any hands raised. So the next question from the chat is two formatting questions. One is the twenty page narrative limit inclusive of references? I don't believe it's inclusive of references. We can confirm that. Yes. And we'll we'll confirm that and include

the response to that in the FAQ document that is posted. Um and the second question is are pages required to be portrait mode. Presentation. Instead of landscape.

I am assuming so. But again I haven't seen that listed out somewhere, but we can confirm it as well.

The next question is if caregivers do not participate in SPROUT, is their SEED child eligible to participate? Um, I can take this one. the answer for that particular question is if we were able to get in touch and they are eighteen years older than they could, the child could participate without the caregiver participating. And they have a hand raised.

Carolyn, go ahead with your question, please.

Thank you. I actually now have a follow up of that question. Plus I have one in the chat plus another one. So sorry about that. So just, just to clarify, so, we would still write it as caregivers being gatekeepers. There'd be only a handful where we actually had contact information of the adult child. I would, I would think maybe like we do for some from component B, but I think there wouldn't be many. Right. Is that we didn't get any information back from um CNI about that. That's right. Any any information that Sanai has for contact information would be provided back to sites.

Um if a caregiver chose not to participate but were to provide contact, updated contact information for their adult child, then that adult child. Oh, okay. Okay, that makes sense. Thanks very much. And, and my other, the question I originally raised my hand about was, is the survey. So it sounds like because you are making this survey mobile friendly, the intent is it, it could be self-administered online or the, the primary aim is to have it self-administered online through the mobile app or website and but could be also by phone by staff.

Is that correct? So yes. Arrange. Yes, that's the intent. Okay.

Thank you. And then, Carolyn, your other question that was in the chat is, do we limit to those who have ASD, DD, or POP classification as in the follow up study? We are actually um yes, but we're also including some of those that who are um classified as indeterminate, who have a sufficient amount of data to be included. We'll provide more details about what those eligibility criteria include, but to answer the question, yes, it's all three of these groups and some from the indeterminate that increases our total pool of potential potentially eligible participants.

Um, but we, we'll provide guidance on how that eligibility criteria, can be determined at your local site. Um, Patrick, could I just follow up on that then, that obviously impacts the budget for the submission. So if are you able to share the, those in advance, or do we just sort of put an arbitrary percentage of additional potential participants? Is that sorry, I just wasn't quite clear on that. We will double check on that answer.

Carolyn. For now, sites should anticipate that they won't get that information from CDC and should. From the available data that you have. Okay.

Thank you. If the indeterminate won't be that many, can I say that? Yes. So, the number of indeterminate case, children that would be added to the eligible pool isn't that many more. So it wouldn't be a substantially higher number than probably what you're anticipating. Okay.

All right.

Thank you.

Thank you. Um, there's a question in the chat from Rob. Our attachments limited to those specified in the NOFO. Um, I will double check. I'm pretty sure it's just the ones that are included in the NOFO, but if there is something that you feel like would be helpful to complete your application, then then go ahead and submit it. Um, and one hand is raised. It looks like that's.

Chris. Go ahead.

Chris. Yes. Actually a question, regarding eligibility to. So I assume given this is really kind of a, let's say remote survey, that eligibility criteria, would not require Participants to still live in the geographic area catchment areas is the original SEED study. They could live anywhere. That's. That's correct. Okay. Um,

Lisa, go ahead with your question, please. Yeah. Thanks. We'll, um we'll see. And I provide all the updated information they got from the people they reached out to for the follow up study. So even so, I think I heard you say they'll provide the updated, any new address information or contact information they found.

Is that, is that what you said? Okay. And then also, oh great. And then will they also provide, the, the, you know, if people said, don't ever contact me again, we'll need the sites. We'll need that information to the no contact list. Yes, we'll, we'll have that. Um and that will be provided as well. Okay. great.

Thank you.

Carolyn. Go ahead. Sorry. I do want to give other people a chance. So I was sort of holding back. Um, I, I found I was just a little bit confused about, some of the aspects of the work plan versus the, and the evaluation and performance measurement plan. Um, the work plan refers to progress or process measures, but links to the evaluation plan which shows performance measures. Is the work plan meant to include different measures than the performance measures. Or is that just a difference in the phrasing that was used. But they're they're meaning the same thing.

Carolyn. I believe it's just the difference in the phrasing. Okay.

All right.

Thank you. And, does is there an expectation that the performance and evaluation plan needs to include additional measures beyond the ones specified in the NOFO or is. Are those the ones you want? And that's the focus. Those are the ones that we've specified so far. Um, if there are any added, those will be based on conversations that happen after. Okay. So they'll be added across the board. So so that's what we would focus on. Okay.

Thank you. I have a few more questions, but I want to leave others to. They're pretty minor. So I want to leave others that have a chance to ask. Okay. It looks like we have one in the chat. Um, are there any planned copyrighted instruments to be incorporated into the surveys, i.e. do we need to estimate a budget for that? And no, there are no copyrighted instruments that will need you. There won't be an estimated anything in the budget for that.

I have a question. Sure. Go ahead. Um, so can you. I'm a little confused about what you mean by data brief and how that is distinguished from public health product. And, so that's the first question. And related to that is the two additional public health products. I think that's what it's called, that are required. But from the site, can those and also the site-specific data brief, can those are those restricted to just SPROUT data or can those include or even be exclusively about previous SEED um data? Um, you know, cycles.

Yeah. I'll take this one. Sure.

Lisa, would you like to take this one?

Lisa Williams. Sorry. Would you like to take that? Sure. The, the data brief is intended to be, an all-site analysis of specific topics that are, determined by CDC. We are currently, envisioning that to be an MMWR. And then the site-specific data briefs will be, the sites individual data that focuses on those particular topics. Um the additional public health products. Um, they can be, anything, that has public health impact from any phase of SEED or SEED follow ups or SPROUT data. So we do want to emphasize that they don't necessarily have to be peer reviewed publications.

Um, they can be things like easy to read summaries or website editions, website updates, infographics that help to explain major SEED findings. And we will certainly talk with sites about what you are interested in, developing and how that can be disseminated. So does that answer your question, Lisa? yes, I just just to clarify the data brief, then you're envisioning, I know it'll be selected by CDC, and the site-specific one will mirror the all-site one. Correct. But is that, is that going to be based on the, the, exclusively on this new SPROUT data that's collected or not necessarily.

Yes. It will, um the, the MMR, the data brief will be based on the SPROUT data that is collected. Okay.

Thank you. And just to add on to that, the purpose of the data briefs and the waves of data is so that we're presenting data in a more timely manner. So we're collecting data in two waves and releasing data briefs in order that we're not waiting until the end of the entire study. Before that, some of that SPROUT data does make it to the public. And so this, this is, this is a concerted, focused effort to bring that SPROUT data and disseminate it publicly, more quickly. And we have maybe two hands raised. Um, Carolyn. Go ahead.

I think Chris was before me. Oh, I did, my question was actually my question was about the site-specific, products, but you answered the question. Thanks. Okay. Okay. Um, this one actually came from Julie, but I think it's a really good question. So I wanted to just confirm, are the response rates the percent of the total or the percent of each level of participation? In other words, is it ninety percent of the total, 65% of the total 50% of the total? Or is it 65% of those who enroll, need to complete the survey and so on?

I have to look back at the way that it was phrased in the NOFO to be sure. Um, if you give me a minute, Carolyn, I can look that up and then answer your question.

Thank you. I do that and then you can move on to the next. Okay.

Lisa, do you have another question? I do sorry for all the questions, but I think other people have these as well. Um, and they just as they occur to me. So this is a question about the

red cap. Mhm. And I understand that, um each site will host their site. Um red cap. Will the red cap survey be designed and, and disseminated to each site. Will it be built for each site. And then we just put it on our own, platform. Yes. So CDC is developing the wave one, survey and it will be distributed to sites, but sites will need to ensure that they do have REDCap access and that maintenance and instruments, are either come from your organization or you would need to download a license.

Okay. And then the, the, the question related to that is, the access to the, the, interface that, that our study participants will use to access that REDCap survey. That's each site will build that interface. For example, a website that has a link to, you know, to get into that know how. We also develop all the survey instruments. And then all you'll need to do is once you have the enrollment call, a survey link will be directly sent to participants. And they should have a mobile friendly format so that participants can answer on whatever device they have handy.

But the survey link will be sent by CDC or by the site by site. But it's all in the CDC developed REDCap database that will be hosted locally by your site. It's integrated into the REDCap instance that you'll be hosting locally. You'll be able to send out those links directly to participants. Okay. And what about, the tracking of the survey responses? And, you know, is that all that tracking system, is that going to be a site designed and developed system or the CDC provide that as well. sites will be doing the recruitment and enrollment.

Um, and there's part of the REDCap database that has all that information that can be tracked. Okay.

Thank you. So I can answer question. Um, in the, in the NOFO where we say 60%, of those eligible enrolled, that's referring to 60% of the total eligible. Um, and then I think the same is true for the percentages that we report for the anticipated number who complete the survey. So about 50% of those eligible caregivers will complete the survey in about 40% of those eligible young adults or children. Child participants will complete the survey. Does that answer your question, Carolyn? Yes.

Thank you. Patrick. It's the total then is our denominator. That's that's right.

I have another question. If nobody else does, it's really minor, but, I'd like to. I didn't quite understand what you meant by participation in meetings of groups interested in the main audiences. I don't I'm not clear what that means. Do you happen to know where in the NOFO that was? Sure. it's under collaboration. I wondered if it meant it was a mistake or just meant findings instead. Um, it's, uh. Page fifty. Participate in meet. You're expected to participate in meetings of groups interested in the main audiences. I think the, the.

Yeah, that's that's a great phrasing, but, I think it's meant to refer to the target audience. So who, who is it intended for? Um, so that you're participating in meetings with the, the partners that are interested in reaching a certain audience, like parents or providers, for instance. Oh, I see, okay, now I understand.

Thank you. I didn't get it. It was again, not, not the best wording, but that's okay. No, I mean, it makes sense now. I just didn't quite understand what you meant. So, I, I actually similarly had a question on what you meant by performance period of the relevant outcomes is that, and then it links to, um the main outcome. So is all that, is that just about, it's in the work plan. And it links to the outcome section which has just the three outcomes. Is that just short term and intermediate or is that linking to the performance measures.

Does that make sense. I'm not sure the question makes sense but. So it says relevant period of performance outcomes from the outcomes section. If you go to the outcomes section, it just has the two short term and one intermediate outcome. I see what you're talking about Carolyn. Um what is your question again? What is what is wanted there is because I would have thought it would be something different from what's in the outcome section. And I just didn't understand if what you were asking for there. So is it just a period of performance needed for by the wave?

So is that is that the only difference? I think that we're referring to there. Right. Sorry. I, I think part of the problem is that this might be a template that was provided that we may need to get clarification from whoever created that. Yeah. Make sure this is yeah, that table is definitely a temp. That was part of the template that was provided to us. So I think my immediate interpretation is that the period of performance is based on the waves of data

collection and then the product search. But that wouldn't make so much sense for strategies two and three, would it?

I'm just wondering if it means performance measures and then it. I don't know that that would maybe make more sense because some performance measures cover the whole five-years and some cover, you know, subsets of that. Yeah. Liz confirmed that and. Okay.

Thank you. Thanks. We have one more question in the chat. The NOFO refers to an adolescent young adult survey. The earlier slide indicated young adult, but not adolescents. Will we be asking participants younger than eighteen to complete surveys? Yes. Yes. And we'll we Lisa, you'll have to help me remember if we had a age, a minimum age for that. But we will allow those under eighteen to participate with caregiver approval. Yeah. We do not have a minimum age, so it will be anyone who can self report. And I see one more hand raised.

Um,

Rob. Go ahead. Yeah. So that actually preempted my question. It was just about for like the SEED three participants who, at least for the wave one will be by my math, like tween, you know, maybe up to maybe fifteen. So we're planning on anyone who can, will and is, you know, parent has, has their parents support will be able to, to answer, the surveys. That's right. Okay.

Lisa go ahead. Yeah. Thanks. Um, in terms of recruitment, are we expected to, for example, we, if we participated in both SEED one and SEED two, are you expecting that we propose to reach all of those C1 and C2 participants? I mean, of those who who you know, who haven't said, don't ever call me again. Um, even if they refuse participation in the SEED or the SEED follow up study, or could we focus on one group or another group? What's the expectation? I think the hope and the expectation was that all participants would be reached out to unless they had specifically said, don't ever contact me again.

Um, to give them the opportunity to participate, even if they had declined to participate in, say, follow up or another person. Okay. I have a follow up question related to that. I'm sorry. I'm having a hard time seeing hands, so I hope nobody else has theirs up. So, If that's the

case, let's say there are a chunk of participants that see and I says are now on the do not call me. I'm not interested in being contacted again list. Are those still going to count in our denominator of the 60% of total eligible that we are required to contact and our numbers for collecting data?

Those performance parameters. No, no. Those would be. So that will be adjusted. Mhm. Okay. I would think they wouldn't be considered to be eligible if they said don't ever contact me again. That's that's right. Right. Okay.

Rob, I see your hand up. Is that a legacy or do you have another? That's just me forgetting to take it down. Sorry. That's okay. And can we get the numbers from CNI soon before we the due date so that we can accurately estimate the numbers of eligible participants will have. I believe, yes, I believe they already have that report ready. Okay, great. And for California, our recruitment was done through CDC. So we'll have to coordinate with whoever you know, the CDC Pi to to then send those on to us, I guess, or we can get them directly from CNI.

That would be great. Yeah. And if the reports already do have a time frame when, when those would be required because it does have impacts on the budget. For many of us, those documents are due next week to our research offices. They are already available. So and they've been shared in the already with the sites. But we'll we can reshare those, make sure that has them bumped up in their inbox. Oh oh. So, so they have the number of participants that would be eligible for SPROUT. Already they've shared with our they have all the information that they have available that is up to date from the current set of participants.

The list of eligible participants from your site. we can provide that pooled estimate, which we already have. But at the same time, there are some instances where there's local site data, where you may have information that would exclude that participant that you'll have to determine on your own. Got it. So does that also include then these indeterminate ones, that we should include because they have enough data. That's right. Okay. Perfect.

Thank you. Sorry I missed that. And it looks like we have one more question,

Christina. Go ahead. I'm just looking at the report that I think is the one that you're talking about, Patrick, that was sent to the sites. And from what I can tell, it's it's not a complete list. It's just people that they actually reach with updated contact information, but it doesn't have information about who said no. Okay. Thanks, Christina. We'll follow up with CNI and get them to add that information. Thanks. Yeah, I think it's the one that went into our into our individual file repositories within REDCap.

But if there's another one I'm missing. Um, another bump in my email would be great.

Not seeing any more questions in the chat. And unless anybody has any other questions right now, we can go ahead and wrap up the call. All the questions that we've discussed today will include an FAQ document that we will be posting to the website, by close business on Friday. Um, if you have additional questions that come up, please reach out. Um thank you. She's just posted, the information here again, so please reach out with any additional questions. Great. Thanks everyone for joining the call. And, the next portion of our call where we, where we will be discussing components B and C will be, will begin in five minutes at twelve o'clock.

Thank you everyone. Seema, will you post the slides or just the, recording or both. We'll also post the slides as well.

Thank you very much. That's very helpful. Appreciate it. Thanks everyone.

Thank you.