SOBC Webinar Transcript
October 26, 2017

Melissa Riddle:
Hello everybody and welcome. On behalf of the NIH Science of Behavior Change working group, I'd like to welcome you to today's technical assistance webinar for several funding opportunity announcements to encourage what we sometimes call "youth inspired research," meant to optimize adherence and other behavior change interventions and outcomes.

There are two broad types of funding opportunity announcements available. For supplementing existing funded studies and these are competing revisions and new exploratory developmental projects. And we'll walk through these later in the webinar.

Before we get into the -- oh, thank you -- before we get into the substance of the FOAs, we want to be sure to handle some logistics and make sure that you can all see the screen and hear the speakers as they talk. First, please know that this webinar is being recorded and I believe will be posted on the NIH website so that folks not able to participate in real time can have access to the same information.

Next, we encourage you to submit questions using the "chat" box, and it should go to Chandra with, as a host. Okay.

Female Speaker:
Look for my name with "host" next to it.

Melissa Riddle:
There may be several [laughs] Chandra Keller-Allens [spelled phonetically] signed in [laughs]. If you look at the "chat" function, but please send questions, anytime, during the presentation to the Chandra that has “(host)” next to it, and we'll do our best to keep track of those and then to ask them on your behalf at an appropriate time.

Let's see, there are several options for connecting by audio, we recommend using the "call using computer," or "call me" options as these are sometimes the simplest. And, finally, as always, I imagine all of you are familiar with participating in conference calls and webinars, we just ask that you keep your phone on mute throughout the webinar to keep the background noise to a minimum.

So, those are our logistics, and if you're having any trouble hearing or seeing the presentation, please also send a note to Chandra Keller-Allen (host) [laughs] and we'll see what we can do to help you. We'll have three presenters today. Dr. Paige Green from the National Cancer Institute will be one of our presenters. She is one of the scientific contacts in the FOAs, Dr. Jonathan King from the National Institute on Aging and, me, Melissa Riddle, from the National Institute of Dental and Cranial Facial Research. Jonathan and I are the co-coordinators of the Science of Behavior Change program.

And we also want to acknowledge that Dr. Will Aklin from the National Institute on Drug Abuse is one of the scientific contacts on the FOAs and together with Paige Green took the lead in developing the FOAs. He's not able to join us today, but he will join us for the repeat webinar next week.

So, here's our agenda. We want to give a little background about the Science of Behavior Change program. We want to talk about the Science of Behavior Change measures repository which is a key element of these funding opportunity announcements. We'll go through the specific announcements, both competing revisions and the exploratory/developmental R21, we'll talk a little bit about SOBC's resources, and then we'll have an extended session at the end for questions from webinar participants.

Just a note about questions, we'll ask that you hold questions about your specific aims or specific research plans, and, instead, direct those to the scientific contacts that are listed in the relevant FOAs.

So, we thought we'd start with some big-picture background of the Science of Behavior Change program. We know that many of you may be familiar with SOBC already, but our hope is that these funding opportunities will engage people new to the program. So, we'd like you to know what we're about.

The NIH Common Fund supports a series of programs that are designed to change paradigms, develop innovative tools and technologies, and provide fundamental foundations for research that can be used by the broad biomedical research community. Common Fund programs address emerging scientific opportunities that no single NIH institute or center can address on its own but are of high priority for the NIH as a whole. And Common Fund priorities must meet -- or programs -- must meet five overarching criteria which are listed on the left side of this slide.

The Science of Behavior Change program is funded by the NIH Common Fund, which sits in the office of the NIH director and, as I said, the NIH Common Fund programs meet five criteria which actually provide a really nice structure for describing the Science of Behavior Change vision. And I'll mention a few of them here.

So, that first criteria, transformative. Our goal is to fundamentally transform the way behavior change research is conducted by infusing the study of mechanisms of behavior change throughout the basic-to-applied research pipeline. And related to crosscutting, unique, and synergistic because so many NIH institute centers and offices have behavior change research programs, the SOBC program has the participation of committed staff across the NIH. And we participate because we see common challenges that cut across our diverse behavior change programs. So, in short, we hope to infuse the study of mechanisms of behavior change across institutes, across behaviors, diseases and translational stages on a large scale that lives on after the SOBC Common Fund program.

And, in order to meet this lofty goal, we do this by encouraging the establishment of an experimental medicine approach to behavior change research as a common method for understanding, promoting, and intervening on health behaviors. And now, I will pass the

microphone and the clicker to Dr. Jonathan King who will describe the experimental medicine approach in more detail along with some examples from public studies.

Jonathan King:
Thank you very much. So, again today what we're going to be doing first is to explain the basis and the thinking behind the experimental medicine approach to behavior change. And, frankly, what we're first seeking to understand is not merely defined interventions that are efficacious as we'll get to, but related to the answer to the question, "What are the processes or mechanisms to drive health behavior change?" All right?

And to do this, basically, we have to answer several questions. We have to have specific hypotheses about targets, by which we mean often psychological processes or specific mechanisms that drive behavior, we need to come up with experimental methods for engaging those targets, and we have to be able to validly measure our ability to engage those targets; so-called "target engagement."

So, the way that this has come into our thinking is by a comparison, albeit and inexact one, with the intervention development pipeline more familiar to our colleagues who work primarily in the drugs and devices world. So, in that setting, for drugs and devices, there's a fairly straightforward -- at least in theory -- pipeline which starts with identifying a target molecule -- usually in most cases -- developing a way to measure whether or not the activity of that target molecule is going up or down or not changing, then finding some intervention that can be used -- so, sorry -- then it's showing that influencing that target actually has an effect on the outcome. Then, finding ways to optimize the specific compounds, usually pharmaceuticals, lead compounds that will affect the target and change its value and, hopefully, therefore cause -- sorry -- cure disease.

There'll be then a series of preclinical studies in animals, and then based on the data come up with to date, the FDA will be given an IND or an I.D. for a device, there'll be clinical trials, an FDA review of the drug or device, and, upon approval, there may be additional effectiveness trials following, but then the drug and device is approved.

For behavior change interventions, there is an awful lot of work that is done, essentially, on several of the steps that you can see in the drug and devices pipeline, but we've noted, from a review of previous projects and our experiences, that a lot of this preclinical activity is somewhat diffuse in nature; it's not as accumulative as all that, nor as systematic. And because there was no especial step for FDA review, the clinical trials that we perform, whether we think of them as stage one, two, or three, often lead to things that are efficacious -- one moment --

Female Speaker:
It's only this computer to sign on the -- webinar.

Jonathan King:
Okay. One moment. I can do it here.

Female Speaker:
I think it's maybe cheaper or some have.

Jonathan King:
Have generated efficacious treatments, but then upon next steps to follow-up, in many cases people are interested in making them cheaper somehow, okay? The difficulty with that directive is that, because in many cases the process by which we came up with the intervention in the first place, were not especially targeted towards the development of specific ways to measure target engagement, would optimize deletes [spelled phonetically], knowing how to make something cheaper or more efficient is difficult.

So, the goals of SOBC in the second phase, was to sort of rethink and recapture that diffuse clinical activity and just has to include the identification at that relations is the targets, which we'll get into. The development of particular assays to measure the target activity, our ability to validate those targets, in other words, to show that affecting the target has some effect on the health outcome. And now, and this is the part for today, to deduce assays into ongoing studies.

Female Speaker:
You've got to move back, again. Sorry.

Jonathan King:
Okay. The funding opportunity announcements that we're interested in you applying to are exactly the ones that will be introducing assays into ongoing studies. You may sort of wonder how that would work or what it would mean, and that's what we'll get to now.

So, again, in the first phase of the Science of Behavior Change Common Fund program, it became fairly clear that although there are potentially exceptions and they're not completely separate in their classification, that there were specific target domains that we felt drove behavior change. So, failures of self-regulation, for example, seemed to be involved in a lot of poor health behaviors, as did patterns of stress reactivity and lack of stress resilience and, in many other cases, it seems that a reasonable way to achieve changed behavior is the interpersonal or social processes.

So, again, the idea here is that we developed a program that would allow people to sort of -- for a given set of health behaviors -- sort of identify targets within you to self-regulation, stress reactivity and stress resilience, interpersonal and social processes that would drive the development of behavior change interventions that hopefully changed health behaviors.

So, just to drill down a little bit. The field of self-regulation, many of you are aware, is not just sort of one atomic thing. In fact, if you look at self-regulation as a target process, it's really a set of target processes. So, again, with some overlap and some conceptually between these things, we can think in many cases of self-regulation in terms of goal setting or planning or cognitive control or, you know, akin to cognitive control in some ways emotion regulation, and, more generally, a process of self-monitoring.

So, during the process of the development of the Science of Behavior Change, many people, our current grantees, have -- I attempted to isolate specific targets within these areas of, and then,

again, find ways of sort of measuring those target areas, and then showing that they would be valid targets of intervention to cause changed behavior.

So, drilling down one more level within cognitive control, one possible process would be attentional [spelled phonetically] control.

Now, in the following slide, I'm going to show you an exemplar that was actually developed from a previous Science of Behavior Change administrative supplement in the first phase of Science of Behavior Change. And, actually, we think indicates the kind of pattern we're hoping people will begin to follow in these competitions.

So, again, if we're thinking in general pre-causal mechanism of behavior change, we know that we can run efficacy trials where we have an intervention, and, at the end of the day, a changed behavior and we can answer the question whether or not its efficacious, but, clearly, in most cases, we don't think that the intervention directly derives the changed behavior. Rather, our intervention is targeted some kind of psychological target of process that we're affecting instead.

In this putative target, that we're attempting to engage, there are really two questions then that together, give us the answer to the question, "Is it efficacious?" And the first, and a question that's -- was, frankly, not asked in as many clinical trials as one expected, is whether or not in the first place whether the target was engaged. In other words, if you had a putative target, these are the case, that your intervention actually changed the activity of that target.

And then, downstream from that, it could have been the case, and maybe is the case in some interventions, that even changing that putative target really has no effect on the change -- on behavior and it doesn't change the behavior. So, you need good answers to both of those questions to decide whether the method is efficacious.

So, this then centers then on, "How do we know what's happening in this putative target?" Well, in many cases we have from basic research areas of interest that will indicate that there is ways of measuring, for instance, the behavior of the participant; there's a behavioral assay that we think will reliably tell us about the putative target or, perhaps, neuroimaging. For things like stress, that is in many cases, the case that we can come up with endocrine assays that will tell us about stress levels. And, actually, in fact, in one project funded in the previous phase of SOBC there was even noted that gene expression changes could occur.

So, the example I'm going to be talking about next will actually be looking at specific intervention, namely attentional bias training, which is, in fact, attempting to target attentional control and change behaviors related to depression and specific assays to measure attentional control will be a behavioral assay and a neuroimaging assay.

So, in the following slide, we're going to be describing very briefly a work by Ian Gotleib [spelled phonetically] who was developing tensional assays and verifying target engagement in his attentional bias training work. Now what is going on here, or what the intent of the idea of here, was to show whether intentional bias training decreases attention to negative or increases

attention to positive affective stimuli, and this will be work being done in at-risk daughters of women with recurrent major depressive disorder.

So, in other words, these adolescents were at very, very high risk of recurrent major depression, and one of the hypotheses about this was that they were showing inappropriate attentional bias. In other words, that in their cognitive system, essentially, negatively biased information was gaining all the attention over a positive bias, and that was the kind of mechanism through which depressive disorder was caused.

So, the way that this worked in attentional bias training, is that actually did, in fact, move behavioral measure of attentional bias, namely, if you look on the left of the figure, if we look at pre-attentional bias training, pre-ABT, of participants were far more sort of pronounced biased towards negative stimuli that in post-ABT in the red, you can see is fairly diminished.

Similarly, in situations where there were positive stimuli, pre-ABT, there was not much of a bias toward looking at the positive stimuli, but, afterwards, there was a healthier bias towards that. So, this is encouraging because it suggests that attentional bias training did what it was supposed to do. It actually was able to teach participants to basically control their attention in a different way, such that they were more likely to experience -- or tend to, I should say -- positive as opposed to negative stimuli.

Now if this were actually the case, we would know from our understanding from cognitive neuroscience, that this change in the tension would essentially gait activity towards negative stimuli that we'd be able to observe in the amygdala. So, again, if successful, what we would expect to see is changes in the activation of the amygdala post-ABT, versus pre-ABT. And, as you can see in the panel in the middle and on the right, and in a region of interest that includes the amygdala, sure enough, there was, in fact, greater activation of the amygdala pre-attention bias training then there was post-attention bias training.

So, in other words, our attentional bias training not only had a discernable behavioral affect in participants, but, actually, led to a direct affect observable in neuro-structures we believe were responsible, or at least involved in depressive behavior.

Okay, so this is the idea of what we're looking behind, and in the point, that we're now discussing here is how to develop these assays that we would like you now to incorporate into your own behavior change work. And so, the three steps that we'll be discussing briefly here are the identification of a specific mechanism, a way to measure our assay of that mechanism, and then a demonstration that you can influence that mechanism or target, and the idea is that once you can change the mechanism, you can change the behavior.

So, how we've been doing this is by work through accomplished by the Science of Behavior Change, or SOBC, research network. And, again, the purpose of the network we've discussed before and what we have asked the projects that are currently funded, too, is identify potential targets for behavior change interventions within three broad domains we've discussed. And then what these -- then what the network members have been doing, is identifying sets of putative targets implicated in medical regiment adherence and at least one other health behavior and then

found ways either to leverage existing measures or develop new experimental intervention approaches to engage identified targets.

So, in other words, first they've gone through and they've decided, for example, that there are areas of self-regulation that they now determined ways to measure and then are now attempting to show that, in fact, intervening on those targets then does have some effect on the outcome behavior.

So, the identification development of appropriate assays or measures is where the network had gotten to this point. And this will now permit verification of target engagement, but not just in their projects, but now also yours. So, we're now testing the degree to which engaging these identified targets produces a desired change in medical regiment adherence and at least one other health behavior in the projects. In your projects in many cases will be a focus on what your trial is focusing on.

Now, very briefly, about where we can find these current assays, these current measures, which is in the SOBC measures repository. So, at present, if you go to the website that's indicated in the -- either in this URL or in the funding opportunity announcement -- you will navigate to the SOBC research network measures repository. Whereas of this morning, there were 63 specific assays in the measures repository including some which were connected with experimental manipulations from the three SOBC domains.

So, if you were to go to the site, or if you haven't been there already, you'll see in the repository that you can sort of -- through a fairly nice interface -- sort of click through and be able to select and hypothesize domain, either all the domains, or one of the three we've mentioned, you can look and see if they're either all the measured types or just self-report measures or just task measures, or just observational ones. You can choose the measure of a duration that would be suitable. For example, for your ongoing trial, because we know in many cases, the protocols that are being developed and used in trials may, in many cases, only be able to accommodate a relatively briefer measure. Although, in some cases it may be -- may be able to include a more expansive measure.

And, again, current you can actually look at things that have been made available and validated for all participants or those that have been focusing on adults or children only. So, again, this is now a screen shot from measures repository. We're not going to walk through the entire thing, but it just wanted to sort of bring your attention to a couple of things including some features that are relatively newer since the launch of the repository over the summer.

So, what's indicated on this slide, is the fact that, in addition to the 63 measures that are currently posted, there are some others that are currently being worked up for inclusion in the repository, the so-called "coming soon" measures. Now, they're not there yet, but they are coming soon in the sense that if you're attempting to put together an application for these funding opportunity announcements, this section of the website will tell you which other assays and measures will be ready for use in your projects even though they're not officially on the website right now.

Similarly, the nice thing about the measures repository includes relatively full documentation on many levels of the measures and how they can be used. So, the open science framework, there's all the measures on the repository are connected to OSF documentation, for those who are aware of that resource, which you can get to by clicking on the obvious OSF documentation link.

There's also the "view details" link for all the available measures which will give you some more information internal to the website that can help you select items for inclusion in your trials.

So, for example, this is the first -- alphabetically the first time this is a tentative personality inventory and the link that's indicated in the upper right would actually take you to the SOBC validation process that led to the inclusion of this inventory in the measures repository including, you know, the steps that were followed to include it there. This is a target that's been identified; we have an ability to measure which is wide and measures repository. And, again, you know, maybe a good candidate for use as a moderator or some other variable in your trial.

And then at the bottom of the detailed information, there are ways, for instance to directly access the measure, as well as visit a link to the actual code or document that you would be using to put the measure into your own work. This is really nice because on an online fashion you can pretty rapidly close in on things that seem appropriate that are well documented, that appear to be appropriate for your population and so forth.

And now, having with that background, we can talk about the specific competing revision funding opportunity announcements. With that, I turn it over to Paige Green.

Paige Green:
Thanks, Jonathan. So, as was mentioned earlier, the NIH Common Fund intends to commit a little over $5 million in FY-18 and another $5 million in FY-2019 collectively across three competing revision RFAs and an R21 RFA to fund a total of 10 to 20 applications. Of course, that funding is contingent upon receiving scientifically meritorious applications and an availability of actual funds.

So, supported by the NIH Common Fund Science of Behavior Change program, three funding opportunity announcements highlighted in the title solicit competing revision applications to NIH supported clinical trials awarded as either research project R01 Grants, research project U01 cooperative agreements, or research project R34 Grants. And a competing revision is a request for an increase in support in a current budget period for expansion of a project's approved scope or research protocol. And so, applicants for a competitive or a competing revision must apply and go through scientific review and I will highlight our review process in a later slide.

So, the three goals of the Science of Behavior Change competing revision FOAs are to one, accelerate the adaptation, validation, and translation or assays in the Science of Behavior Change measures repository for use in ongoing clinical trials as Jonathan spoke about a bit earlier. Also, we seek to integrate assays in the Science of Behavior Change measures repositories into active, NIH supported clinical trials of drugs, devices, procedures, or behavioral modifications.

So, as such, the active clinical trials used to respond to these announcements does not have to be a behavior change trial or identify behavior change as a primary outcome. We really envision that the integration of the Science of Behavior Change measures repository assays into these ongoing clinical trials will accelerate the developments of interventions and experimental manipulations that have been shown to engage specific mechanisms of behavior change and the development of assays that verify engagement of those behavior change targets.

So, our overarching research goal or objective is to encourage the adaptation, validation, and verification of assays in the repository that are meant to engage and verify engagement of behavior change targets hypothesized to be malleable and responsible for behavior change.

So, in terms of eligibility of the types of clinical trials, as mentioned earlier, applicants must use an NIH supported clinical trial as the empirical context for target verification or validation, engagement through experimentation or intervention, and examination of the degree to which that engagement produces a behavior change. That behavior change must be relevant to the purpose, goals, or outcomes of the parent trial.

It's important that we note that relevant R01, U01, and R34 awards across all stages of clinical trial or intervention development are potentially eligible. We encourage you to confer with a parent award program official at the institute, center, or office that administers the R01, U01, or R34 award that you are thinking will serve at a parent trial of -- for applying to this -- to these funding opportunity announcements.

So, let's talk about the scope that we're seeking for revision applications.

So, we require the following elements for your revision activity or aims. We require that you include a well justified scientific rationale or theory for the selection of the putative target or mechanisms of action, that you use one or more assays from the Science of Behavior Change Measures Repository, and that you identify a behavior change outcome that is relevant to the parent trial.

Revision applications can support a significant expansion of scope or research protocol approved and funded for the parent trial. The justification for the scope expansion should include clear rationale or theory for the mechanisms of action, by which the intervention is hypothesized to cause a behavior change outcome relevant to the parent trial. So, the research scope of the revision application must address the goals of the Science of Behavior Change program as outlined in the FOAs, and activities and aims proposed in the application must, as you can see on the slide, identify a putative target from one of the domains implicated in a behavioral outcome relevant to the parent trial. And secondly, you must engage the identified target or verified target engagement by using one or more essays from the repository.

Further, activities and aims that test the degree to which engaging the putative target produces a desired change in a behavioral outcome relevant to the parent trial are encouraged, but not required to be responsive to these competing revision FOAs.

Applications that do not propose to use at least one measure assay or experimental manipulation from the measures repository will be deemed non-responsive, and will not be reviewed. So, I won't belabor this point, but you can see on the slide the two critical elements that responsive applications will achieve in their applications.

Let's talk about budgets. So, for the R01 and the U01, the budget that can be requested is limited to $500,000 per year in direct costs. The R34 revision applications budgets are limited to $225,000 per year in direct costs. However, it is important to note that your budget request cannot exceed the budget of the parent award, that your budget must actually reflect the needs of the proposed revision activities and aims, and you must consider the requirement as outlined in the FOA to attend the annual Science and Behavioral Change Research Network Steering Committee Meeting in fiscal year 2019. Those meetings are generally held in January and last approximately two days.

In terms of project period for the competing revision, the maximum project period allowed is two years. However, the scope of the proposed project should determine the length of the project period, and most importantly, the project period of the revision application cannot extend beyond the end date of the parent award.

We do have a very explicit data sharing plan. So, scientific integrity, collaboration, trust, openness, respect, rigor, and transparency really undergird the foundation of the Science of Behavior Change research network as an NIH common fund program. So, all applications are expected to include and adhere to a data sharing plan that includes commitment to data sharing and explains the procedures for sharing protocols, data, and results obtained using funding through these FOAs, and that data sharing should be primarily with network members and the public. And all awardees are expected to have an open science framework account and a public facing open science framework study page linked to the Science of Behavior Change OSF website. More information about our resource and data sharing plan expectations are outlined in the FOA.

In terms of review, applications submitted will be reviewed by a special emphasis panel convened by the NIH Center for Scientific Review. Reviewers will evaluate the potential of the application to advance the implementation of a mechanism focused experimental medicine approach to behavior change research, and you should read this section carefully because we have included specific scored review criteria for significance, innovation, and approach. And I won't go into those there, but they're nicely delineated in the funding opportunity announcements, and if you have questions, we can address them during the question and answer period.

So, let's turn our attention now to the R21 funding opportunity announcements.

So, again, supported by the common fund, we are soliciting exploratory and developmental research project applications which are known as R21s to advance a mechanism focused experimental medicine approach to behavior change research. Our goal or objective is to encourage the adoption, validation, and verification of assays from the measures repository that

are, again, meant to engage and verify the engagement of behavior change targets that are thought to be malleable and responsible for health behavior change.

So, activities and aims supported through the R21 FOA must be based on a well justified scientific rationale for the relevance of the selected putative targets or mechanisms of action from the domains that we focus on in the Science of Behavior Change, and their relevance to a change in a health behavior. The R21 project must leverage at least one Science of Behavior Change Measures Repository assay to do the two things that are outlined on the slide: to engage the putative target, or verify targeting engagement of the selected target and, two, to test the degree to which engaging the target or mechanism of action produces a short-term desired change in a health behavior.

Applications that do not propose to use a Science of Behavior Change Measures Repository assay or experimental manipulation will be deemed non-responsive, and will not be reviewed. And, again, the responsive applications will identify a putative target, use one or more assays from the repository to engage the identified target or targets and verify target engagement, and, thirdly, test the degree to which engaging that target produces a short-term desired change in a health behavior.

In terms of allowable budget, just like a regular R21 mechanism, the direct cost for the two-year project period may not exceed $275,000, and no more than $200,000 may be requested in any single year. Again, as with the competing revision FOAs, your budget request must reflect the actual needs of the proposed revision activities and aims and, again, it is important to include the requirement or consider the requirement to attend the annual Science of Behavior Change Research Network Steering Committee Meeting in fiscal year 2019.

As with all R21s, the scope of the proposed project period should determine the length of the project period, and the maximum allowed project period is two years.

As mentioned for the competing revisions FOA, the fundamental principles of the research network are founded on scientific integrity, collaboration, trust, openness, transparency, rigor, respect, and so all applicants or applications are expected to include and adhere to a data sharing plan, and I won't go through the specifics again as they are exactly the same as that that we reviewed during the competing revisions FOA.

Again, applications in terms of review will be reviewed by the special emphasis panel convened by the NIH Center for Scientific Review. Reviewers will evaluate the potential of the application to advance the implementation of a mechanism focused experimental medicine approach to behavior change research, and specific scored review criteria are included for significance, innovation, and approach. And it's important to note that there are some slight differences between the criteria that are outlined in the R21 FOA and the criteria that are outlined in the competing revisions FOA for the R01, U01, and R34 mechanisms.

Okay, with that, I'm going to turn it back over to my colleague Dr. Riddle to walk us through some resources that we have.

Melissa Riddle:
Thank you. All righty. Sure, yes, sorry.

[laughter]

Paige Green:
New plan.

Melissa Riddle:
Paige is going to continue to walk us through, yeah.

[laughter]

That's okay. So, as alluded to earlier, it is very important to read the funding opportunity announcements carefully, and in the slide, we have included the URLs for the four funding opportunity announcements that this webinar has focused upon. Here are just some of the important dates that are outlined in the FOA. The earliest submission date is November the 5th. The letter of intent due date is November the 5th. However, as noted, that the letter of intent or letters of intent are not binding. The application due date is December the 5th by 5:00 p.m. local time of your applicant organization, and the expiration date is the next day. So, there'll be no extensions unless we have another major natural disaster.

Paige Green:
Hopefully not.

Melissa Riddle:
Hopefully not [laughs]. We really encourage you, especially for those of you that are less familiar with the Science of Behavior Change, our history, and the amount of very important work that has been done up to this point, to really use the Science of Behavior Change Common Fund Program website. On that website you can find more information about the research that has been funded, not only during this second phase of the size of behavior change, but also in the first, and there are other resources like frequently asked questions. I believe that the webinar documentation will be posted also on this website page as well. So, take advantage of the information that is collected on our website.

As Jonathan so nicely pointed out, it is imperative that you use the Science of Behavior Change Measures Repository. And we really do want to use this time to sort of thank, thank all of the funded investigators that have contributed their assays, their measures, their experimental manipulations to the repository, and also extend our thanks to the Research and Coordinating Center at Columbia for compiling this website and this repository. You can see -- Jonathan highlighted that there are several ways that you can get to the measures repository through the open science framework link that was highlighted in previous slides, but you can also use the link that's down at the bottom of the slide. And if you have any questions, please do send those questions to the information box URL that is noted at the bottom of the slide.

And lastly, we really encourage you to connect with the Science of Behavior Change programs staff. My colleague, Dr. Will Aklin, is the principal contact for the series of funding opportunity announcements. So, do reach out to him. However, we work very closely as a team. So, feel free to contact any one of us that are listed as the primary scientific or the scientific contacts in the FOA. But also, we have a large group of colleagues across the NIH that are invested members of the Science of Behavior Change Working Group, and so if you have particular scientific questions that are relevant to a particular Institute, we might actually work with you to connect you to that working group member.

Okay, and at this time I think we can transition to taking your questions.

Q&A

Chandra:
I just received a question, the last question, but I know we have a slide on it so I'm going to do that one first. What information is required in the letter of intent?

[laughter]

Paige:
Well, thank you for that question ---- and we anticipated it. So, this is the information that is required in the letter of intent, and none of this is binding, although I would hope that your name and address and stuff would remain consistent. But there's a scribed title of your proposed application, the names of other key personnel, the institution that you're from, and it's important for us to know which of the four funding opportunity announcements you intend to submit an application to. Do you have something else to add to that?

Jonathan King.
Just to point out the use of these letters of intent are for us to gauge not only the relevant response to the FOA, but also, we can then forward them to the Center for Scientific Review who will be reviewing many of these applications and are helping to hopefully identify some of the reviewers as early as possible in the process to make sure that we can cover the appropriate science in your application.

Chandra:
Thanks Jonathan. Okay, okay, I'm going to group these together a little bit. We have some questions focused on the measures repository, and then we have some questions that are specific to the revision. The measures for repository questions: will additional measures to be added to the interpersonal processes domain? If so, what is the timeline? If not, if we include the one measure list for adults and add other measures not listed, will be application be considered responsive to the RFA?

Melissa Riddle:
So, I'll take that one. This is Melissa Riddle, and I have an interest in the interpersonal measures domain. So, I know that there are several candidates for assays and experimental manipulations that the team is considering putting on the repository. I don't know of a timeline, but the

important part, I think, of that question is that, yes, if you include at least one essay or experimental manipulation from the repository, so I think you mentioned the adult one, then after that, you know, as other assays or manipulations become available you can add those or not. But your application would still be responsive, so you need at least one assay or experimental manipulation and, Chandra, maybe I can answer that question about assays versus experimental manipulations.

Chandra:
Sure.

Melissa Riddle:
There was one question about is it okay to add an experimental manipulation or must you add an assay for the revision application? And the answer is you need to add -- use something from the SOBC repository. So, it could be an assay, or it could be an experimental manipulation.

Chandra:
I think maybe that question you're thinking of is: are applicants limited to adding additional measures or may they propose an additional intervention arm? That was a revision question.

Melissa Riddle:
Oh, okay, okay.

Chandra:
But your other answer was good too.

[laughter]

Jonathan King:
In the [unintelligible] additional intervention arm.

Chandra:
Right.

Jonathan King:
In particular, for some ongoing clinical trials it may be particularly, if there is a DSNB involved, that they would prefer use of new measures in the protocol to be in a different arm of the trial.

Melissa Riddle:
Yeah, or even a sub-study.

Jonathan King:
Or sub-study, correct.

Chandra:
Yeah.

Jonathan King:
That's fine.

Paige:
But the key with that is that if you're not adding an assay from the repository, you need to have some tool from the repository in your proposed study. So, if the additional arm is an experimental manipulation from the repository, that qualifies. If you add a measure assay from the repository to the additional intervention arm, that qualifies, but you have to incorporate something, a tool from the SOBC repository.

Melissa Riddle:
Can I just add to that that we also want to highlight that your selection of a particular assay or measure or experimental manipulation from the repository must be grounded in a well justified scientific rationale. And we also recognize that, while there may only be one measure that's sort of classified under the interpersonal and social domain, for example, that many of the assays, measures, and manipulations can be conceptualized or theorized as fitting in one or more of the domains of interest. So, it's really up to the potential applicant to sort of outline why they have selected to choose a particular assay, and the theoretical conceptual scientific justification for the inclusion of that assay, experimental manipulation, or measure in their application.

And we've used the term assay just as the short nickname or for, you know, saying measures, experimental manipulations and assays. So, they are -- it's s just one common term that we made a decision to use to reflect the buckets of things that are in the measures repository.

Chandra:
Okay, I'm going to follow up with two related questions about the repository. So, there's a question about the timeline of: will more measures be added to the repository by the December deadline? I believe that the coming soon box: if you click on that, there's a list, and I believe that the timeline for those is intended to be before the deadline. And then the follow-up question, which was part of the previous question as well is: can the applicants add -- if they take one assay from the repository, can they also use additional measures of their own?

Jonathan King:
And the answer there is yes.

Chandra.:
Yeah.

Jonathan King:
And in many cases, particularly for the R21s where it's explicit criterion, we may be very interested in finding out whether the measures being developed from the repository give results consistent for others that are being used in the field, in your trial, or in others that are supposed to be measuring the same target. That's perfectly fine.

Chandra:

Okay, I have a bunch of questions about the revision. Can the parent award be from any Institute or Center?

Chandra:
Yes [laughs].

Jonathan King:
Yes, the NIH common fund is -- all of those funding opportunity announcements are on behalf of all of the Institutes, Centers and offices that actually make awards. So, as were we were reminded, the Center for Information Technology does not make awards.

[laughter]

But, basically, yes, that is true. Now the one thing we did, in fact, encourage in the FOAs is that you be in contact, particularly with the program official for your trial, in addition to us because, in some cases, it may be the case that the program staff from that Institute or Center would be more or less supportive of what particular thing you're attempting to provide. At the end of the day, even though everyone is eligible, the Institute, Center, or office that is responsible for the original award will also have to approve the competing revision onto the project. And if they have reasons not to make that award, then they will do so.

Female Speaker:
[inaudible]

Jonathan King:
Correct, so one of the things that happens in some of these cases, perhaps more often in the case of administrative supplements than for competing revisions, is for projects that have large unobligated balances; in other words, projects, trials that, for instance, have not been accruing at the level anticipated. So, this is not basically -- it shouldn't be construed as an attempt to allow you to gain more funds to catch up on a trial that's not accruing or similarly add to a previously large, existing body of funds that perhaps could be used to support the study. Yeah.

Chandra:
I have two questions about the PI of the parent award that are related. Can the competing revision PI be a different person than the parent award PI?

Jonathan King:
The answer there is no. The answer there is no. Unfortunately, as it turns out, the principal investigator for the competing revision has to be the same as the principal investigator of the trial. That said, there are situations where, for example, a multiple PI can be added at the Institute's prerogative into a project and then an additional investigator can be named on the competing revision. They just have to match the parent award.

Okay, so we have had situations in the past, and many of you may have seen them, where additional investigators have been added as multiple PI's, and then a competing revision,

ironically, has to include those multiple PI's, even if they are not, perhaps, germane to the specific topic involved. That's a good question.

Chandra:
Yeah, right, and just so the person doesn't think I skipped their question, there's another one: does the PI for the award need to be in the same institution as the PI of the parent award, and since Jon just explained --

Jonathan King:
Yeah.

Chandra:
-- it has to be the same person: then that would be, yeah.

Jonathan King:
Yeah, yeah, and there is one wrinkle there though too which is that, again, the application is coming from the institution who is the actual grantee. So, in some cases we have situations where PIs have multiple affiliations. Just to point out that the application should be submitted by the grantee, the institution for the original award, and not one of the other affiliations that are available to the investigator. And you wonder why I mentioned that? Because we did have a case --

Chandra:
Yeah [laughs].

Jonathan King:
-- and it did not go over well.

Chandra:
No. Okay, for the revision applications is clinical trial defined using the newer, broad definition from the NIH notice NOT-OD-15-015? And the answer is --

Chandra:
I think it can, yeah.

Jonathan King:
[unintelligible]

Melissa:
Yes, so the definition actually isn't new. The definition was announced October 2014. So, the definition is becoming an issue because a number of new NIH clinical trial policies have been released recently. But that definition is not particularly new, and actually I think it serves us as, you know, it serves the purpose of all of these funding opportunity announcements: to use the broad definition because we want we want to infuse this experimental medicine approach as broadly as possible. So, we're going with the broad definition, yeah.

Paige:
And as I outlined, you know, during the presentation, we really are encouraging any clinical trial/intervention along a sort of very wide developmental continuum. So, it can be exceptionally early phase, proof of concept, all the way to effectiveness, efficacy and effectiveness trial.

Jonathan King:
One thing to note here is that it does say the applicant must use an NIH supported clinical trial, which is true, and given the definition, that's fine. It's encouraging and perhaps, if in fact the trial was in fact registered as a clinical trial, when submitted, if that's the situation, the four more requirements than just being an NIH defined clinical trial. But the all stages comment is very relevant here because, in many cases, people are doing work that now NIH clearly considers to be clinical trial, but it could be relatively early stage research, and those are perfectly acceptable for these FOAs.

Chandra:
Okay, I have a follow-up question about the multiple PI question. To clarify, you can't just add a multiple PI to the revision application. The multiple PI has to be added to the parent award.

Jonathan King:
So, I think that is a situation where there may be some difference between institutes and centers.

Chandra:
Oh.

Jonathan King:
I believe formerly and technically it needs to match. But I believe it will be referred to the Institute or Center if there is a multiple PI added on the competing revision. This is a case where I would definitely ask the program official for the institution for the clarification because, in most cases, the addition of a multiple PI actually is relatively straightforward and not very, not very difficult. But, again, I would definitely defer to the program official for the trial you're attempting to revise.

Melissa Riddle:
Yes, and I would also add, at least in the case of the National Cancer Institute: it's also important to direct those questions to your grants specialist person --

Jonathan King:
Right.

Melissa Riddle:
-- and, you know, the Institute's business office that handles your notice of grant award. It's also, I think, very useful to connect with them if you're thinking about submitting a revision application because they can tell you whether or not your unobligated balance or your carryover is at the point, if that should happen, in which this would make it a bit more difficult. So, work with your -- you know, with whomever is the program official or program director, but also try to confer with your grants management specialist for that particular award as well.

Jonathan King:
So, again, just to clarify: the common fund is the source of the funds for these awards, but, particularly in the case of revision awards, these are already being overseen by specific Institutes and Centers and their policies and procedures are still quite relevant, despite the fact that it's a common fund award.

Chandra:
A quick question I can answer. Will there be another webinar? Yes, we are going to do a repeat on Monday, October 30, at 12 p.m. -- Oh, look at you -- at 12 p.m. Eastern. It'll cover all the same content, but we might get a different set of questions, so, if you want to join that one as well, go back to the SOBC Common Fund website and click. There's a separate registration link for webinar number two, and you'll get the WebEx information if you register for that one separately.

Follow-up on that letter of intent question, just to confirm: the LOI does not require an explanation or summary of information about the proposed activity, but just a descriptive title at this time. That is correct.

Jonathan King:
That's right. As I mentioned, letters have been sent primarily for us to have some notion of what things are actually coming in. Then, also, to give notice to CSR about the expected number of applications, the applicants, and the PIs, just so they can keep -- start to build [unintelligible] as can be.

Chandra:
All right. Are there financial eligibility issues, such as, can the PI applicants be currently supported by another NIH grant, as a Co-I [phonetic], for example?

Jonathan King:
That question seems unclear to me. Unless you're talking about a situation -- I -- if the person can hear me, if you could rephrase that in a way so it's clearer what you mean. One possible meaning for this, I suppose, is that if you're intending, for example -- sorry -- do a competing revision to one award when the actual work will be happening in a different award; don't do that.

Chandra
Jonathan King:
Why I mention that is because one person did ask me if they could, for example, do an R21 where the award was actually going to happen in a different grant that wasn't of the mechanism enlisted, and the answer is, generally not.

Paige:
Yeah. And I heard that question as, is there a cap on the amount of funding -- yeah, that's what I thought.

Jonathan King:

Oh.

Jonathan King:
-- allowed, so that if you're already funded --

Jonathan King:
Right.

Chandra:
-- on another grant, and you get to some sort of cap. But I'm just making this up, so -- okay, the person actually just clarified it was really a question about can the PI be a different PI on the parent [inaudible].

Jonathan King:
Okay; we have to put that one, yeah.

Chandra:
And we answered other questions.

[laughter]

Jonathan King:
One question that may come up is in some cases people with career awards, for example, me being interested in an R21 opportunity, in particular, and the interest whether or not they're eligible to apply now it gets back to the specific institute, center, or office that's supporting their [unintelligible] award. And then, A, the answer, I know, is to -- it's another [unintelligible]; sort of depends on there's an overlapping science and whether it can be construed as consistent with the training plan that's [unintelligible].

Chandra:
Okay. For the R21, how many health behavior outcomes are needed; if the study includes multiple different measures of medication adherence, is another health behavior needed as well?

Jonathan King:
No.

Chandra:
Is the health behavior --

Jonathan King:
Is the health behavior, and one of the prime concerns actually of a sub-EC [phonetic spelling]. In the slides -- it's often shown in SOBC presentations, but not in this one, one of the most discouraging facets of our work at NIH is in situations where we've discovered a perfectly efficacious medication that people don't take. So, a specific example, for example, is the case of statins, where a lot of people, even after a heart attack, are not actually adherent to their prescribed statin, which is a concern and a worry because we know that it helps, and one of the

things NIH is very crazy on, interested in, is making sure that when we've turned discovery into help, that the, sort of, health [inaudible], because people aren't doing what they're supposed to. Yeah.

Chandra:
Are international sites supportive?

Melissa Riddle:
I believe so.

Chandra r:
Yeah.

Jonathan King:
When components are allowed -- the question is, are foreign applications allowed?

Chandra:
Yeah. Well, in our case, non-domestic entities, foreign institutions are eligible to apply --

Jonathan King:
Okay.

Chandra:
-- non-domestic components of U.S organizations are eligible to apply, and foreign components as defined in NIH-grant policy statements are allowed.

Jonathan King:
Great. That's a good point, though. In some cases, in other RFAs, it may be the case that foreign institutions are not allowed. And for some activity codes, they can only be allowed under an exception.

Chandra:
Okay; another clarification. The PI is located in the U.S. --

Jonathan King:
Right.

Chandra:
-- but the clinical trial is being conducted abroad, is that okay?

Male Speaker:
So, if you're talking about the PI, you're talking about the institution, or the student, yes, I mean --

Chandra:
Yeah.

Jonathan King:
-- because foreign awards are also allowed, although they meet those -- okay -- stepping back one --yes, because we are allowing foreign applications, it would be okay even if the award were to a foreign institution. If, however, the award is proposed to a foreign institution, most of the [unintelligible] do require a special council action to approve such an award. That's, again, something you should really talk to your program staff in advance about.

Chandra:
Okay. But that wasn't his question.

Jonathan King:
No, but --

Chandra:
He's -- we actually even have an SOBC award currently that --

Melissa Riddle:
Right [unintelligible].

Chandra:
[unintelligible]

Jonathan King:
That's correct. You can actually look up at the SOBC website and Johannes Haushofer; his clinical work is actually all being done in Kenya.

Chandra:
But he's based in the U.S.

Jonathan King:
He's at Princeton, yes.

Chandra:
Okay. For treatment adherence, could you mention a few targets?

Jonathan King:
This is a good point. So, for adherence, a lot of the action has been either on whether or not people have sort of the -- well, basically the sort of self-monitoring, self-control kinds of aspects of one thing. Or another situation is if people are not adhering because of other stressors, things that are happening in their lives. But this is actually a situation where I think adherence, regimen adherence, is perhaps particularly amenable to a social --

Melissa Riddle:
Interactional [phonetic] --

Chandra:
Yeah; yeah.

Jonathan King:
So, not to give too much family history, but there was a member of our family who would not do as told unless you really controlled, in which case you heard the statement, "Well, if it makes you happy, then I will."

Melissa:
[laughs] And that's one way it could go, or it could go the opposite way, which is "Don't tell me what to do."

Jonathan King:
But if there are ways to get to "yes," particularly from an interpersonal perspective, that is -- it's known in literature as one of the few routes to adherence for those who are not adhering.

Melissa:
Right. And the ones that are -- the one interpersonal project that is funded through the SOBC network right now focuses on coercive processes.

Jonathan King:
Yeah.

Melissa:
Among couples, it has to do with adherence, actually, so if you're interested in that, check out coercive processes.

Melissa Riddle:
[affirmative]

Male Speaker:
Okay.

Melissa Riddle:
I just want to add that, you know, it's important again to pick, you know, potential targets or mechanisms that you hypothesize are malleable, can be changed --

Paige:
Uh-huh.

Melissa Riddle:
-- and are, in your conceptualization, directly linked to your outcome, so, in this case, treatment adherence.

Jonathan King:
Right.

Chandra:
Okay. Is there a relative preference for studies that include experimental manipulation, adding a new arm, or is it those that are using multiple measures from their repository, and then using statistical methods to uncover potentially multiple -- sorry, I missed the last word there -- multiple mechanisms.

Jonathan King:
Yeah.

Melissa Riddle:
Where [unintelligible]

Chandra:
No. [laughs]

Jonathan King:
No. I mean, if they're responsive, it will be done in the interest and quality of the science, and responsible applications. And I can imagine either of those things being very useful --

Chandra:
Yeah.

Jonathan King:
-- depending on how, again, the details of how they're done.

Chandra:
Yeah; sure.

Melissa Riddle:
Yep.

Chandra:
Okay. Are there sample applications available to view? No.

Jonathan King:
Not NIH. And actually, one point I can make is there are people who are interested in seeing applications from their institution, and they're successful, and they have questions about grantsmanship [phonetic] questions.

Many office-responsive [phonetic] programs do actually have ways you can see those, and coaching available there. In some cases, we tell people to look at, for example, things that are in NIH Reporter to see what kind of work's been funded in the past. That is, perhaps, less helpful, unfortunately, to these RFAs because we're telling people to do things that haven't been --

Melissa Riddle:

[unintelligible]

Jonathan King:
-- funded, or done much. So, unfortunately, that's one of those situations where as a matter of course we treat applications as sensitive documents, and so either successful or unsuccessful applications are not publicly available, in general.

Melissa Riddle:
Right. While we might not be able to help you by giving you examples of successful applications, I think this is another reason to connect with one of the scientific contacts that are listed in the FOA, or your program official, or one of the Science of Behavior Change working group members.

We, most times, are very happy to sort of hear your ideas, hear your specific aims, read a specific aims page and give you some feedback that, of course, is just our opinion [laughs], expertly guided, but our opinion; we are not your peer reviewers, so, you know, if you need some additional guidance on, you know, how to frame your specific aims, I think that we will do our best to make sure that we provide you the type of consultation that will help you be successful.

Chandra:
Okay. I'm not 100 percent sure about this question, so maybe the person can clarify. "Are you at all open to answering questions without a specific aims page yet?" My first question about that is, do you mean right now, or do you mean when you call your -- the scientific contact? And then, it says, "There are no example-funded R21s"; I'm assuming she means in the SOBC's program? And this person had brought some broad questions about the R21s. She said the word "mechanism," but I think she means activity code. So -- and then she says, "When should you call a scientific contact?"

Jonathan King:
Okay. So, from the Science of Behavior Change website, it does link to the projects that you currently fund UH-2s, for example. And there haven't been a round of R21s funded through SOBC, actually. So, that -- that's right; this is a new activity. And the idea of having exploratory and developmental applications here was precisely because many people, when they're developing new interventions, can use an R21 to explore, for example, whether or not the mechanistic hypothesis they have in mind, which they hopefully can help test the available assays, will work. So, this is -- that is the -- that's the crux of it, I think.

Melissa:
I'm hearing that this is a person relatively new, maybe, to grant writing, and would like some sort of fundamental coaching and that's fine. At least -- yeah -- you can call any of the scientific contacts without having your aims written, and then just discuss.

Melissa Riddle:
Yeah.

Chandra:

Yeah.

Paige:
I would say, though, that just a professional preference for me -- while I'm, you know, while I'm very happy to have an initial conversation, in order for me to feel relatively confident in the type of guidance that I provide, I always like to encourage a second conversation in which you have fleshed your ideas out a bit more concretely, and you can have send me something, even if it's still in draft form, that I can react to, and that I can actually share with colleagues that I trust to sort of make sure that we're giving you the best guidance. So, I don't think it's absolutely necessary for the first sort of conversation, but definitely the more information that you're able to provide, the more, you know, we can sort of provide guidance to you. Along, you know -- non-binding, but [laughs] just guidance. That's how I approach it.

Chandra:
Okay. I have a question about the timeline. "When will successful grants be awarded?" And we can have that one first, and there's a follow-up.

Jonathan King:
So, right. So, given the due dates for these, these are going to be -- we are intending for these to be applications that will be reviewed by May council. After May council -- in other words, basically after they've been reviewed, and after council's cleared, the earliest start date is listed as July 2018, and that's because that's the -- that is the earliest available start date for May council applications. That said, we -- those who are familiar with NIH know that sometimes just because it says July when it's available doesn't mean the award will happen on July 1. They must be, however, made by the end of September -- September 30th of 2018. If I had to guess, I would actually say that the actual awards are probably are more likely in late July/early August.

Chandra:
Yeah.

Jonathan King:
But we do like to get these out the door. This is not one of those situations where we're really running up against the end of the fiscal year, as in some of our other RFAs that may be out in the street. Yeah.

Chandra:
Okay. A related question. I know Paige addressed the end of the timeline in her presentation about the revisions. This person is asking, "Does the start-up date of the new revision have to line up with the parent award recycle date?

Jonathan King:
Oh, no. No, it doesn't. So, the way that that works -- that's a good question now -- is that if it fits -- for example, if it's two-year competing revision, they will make the award, okay, on to the appropriate year of the project, and then if it's the second year of funding, that will probably be lined up with the recycle date of the award because the competing revision amount is then included in -- in the second or subsequent year, it's included as part of the parent, then. And if --

Chandra:
[inaudible] handle that administratively?

Jonathan King:
That's an administrative -- right. That's a detailed question where the grant specialist can definitely be of greater help than we can.

Chandra:
Okay. This might be a question that you will refer to talking to a scientific contact. "How about measuring the ability to follow treatment-relevant verbal directive? Is this relevant to SOBC?"

Jonathan King:
So, most verbal directives are part of the medical regimen, and if you can be documenting what you're -- what that is -- what that regimen is, and how you'd be intervening on it, that should be appropriate.

Melissa:
It sounds to me -- I agree -- it sounds like it could be; it depends on how that fits into your conceptualization of a treatment adherence, and then what specific mechanisms you think, or targets are at the right level of analysis, that you would manipulate them and measure their engagement, and -- but it could be.

Jonathan King:
Yeah, I think it would be careful -- it would be important to show that specific physician directives you're talking about really are part of the medical regimen, and not just, "I do what my doctor says" is a routine basis, where --

Female Speaker:
Right.

Jonathan King:
-- where that would be less -- not that that's a bad thing to do, it just would be more difficult to construe a trial or construe a research study that had a looser interpretation there.

Melissa Riddle:
I might add that I believe that on our Frequently Asked Questions page, we have some, you know --

Jonathan King:
Right.

Melissa Riddle:
-- right -- some answers that address sort of what we -- how we are conceptualizing medical adherence, or medical regimen adherence --

Jonathan King:
Right.

Melissa Riddle:
-- and that might help guide a more informed answer to your question.

Jonathan King:
It is fairly open, but just as a practical matter, it's much easier to determine whether or not adherence improved if --

Melissa Riddle:
Yeah.

Male Speaker:
-- it's a very -- if it's clear how to score that.

Chandra:
Okay; a follow-up to the timeline question. Maybe I'm not translating these very well. "If the parent award begins July" -- that's 2018 --

Jonathan King:
Oh, so this is a person --

Chandra:
Okay; wait.

Jonathan King:
-- who is participating in an award. Okay; that's a different question.

Chandra:
I don't know. This is -- okay, I'm going to read exactly what it says, because maybe I'm interpreting things incorrectly. "If the parent grant begins July 2018, and this" -- I'm assuming the revision -- "is awarded in August/September, data collection cannot start until the next year?"

Jonathan King:
Okay. So, I think there's three different issues here. One issue that has happened in the past is for a competing revision to be awarded, the parent award has to be awarded.

Chandra:
[affirmative] yeah.

Jonathan King:
That's actually also true at the time of application. A competing revision application will not be accepted until there's an award it can be associated with. This is unfortunately a problem sometimes because you can come up with situations where it's very clear that an application will be awarded but has not been awarded yet, and then you'll find that the system will not allow you

to submit a competing revision application. In terms of the question, I think I'm hearing from the person -- this is perhaps one of the more confusing aspects of NIH, which is that we make awards specific dates that occur by definition one fiscal year or another. But an award made July of 2018 is in fact a fiscal 2018-year award, okay, even though much of the money will be spent in fiscal and calendar year 2019.

This is something that always confuses, but the idea is simply that over the 12-month period between -- or between the period of, you know, the award and whenever the next award date is for the type 5, that, you know, activities are occurring that are consistent with that. Yeah, I -- and, again, this is a situation where if there really is a concern about, for example, awards and things of this nature grant specialists are very good at being able to tell you -- what are you looking for?

Chandra:
No; keep going [laughs].

Jonathan King:
All right. Grant specialists can be extremely important and valuable in making sure that these things are lined up correctly --

Chandra:
Yeah.

Jonathan King:
-- which is why we do recommend, particularly for competing revisions, you talk to them first.

Melissa Riddle:
Yeah. I just wanted to point out that on 528, down at the bottom, the URL has the NIH link to --

Jonathan King:
That's right.

Melissa Riddle:
-- to competing revisions, then eligibility --

Male Speaker:
Right.

Melissa Riddle:
-- and sort of -- so that might give you additional guidance.

Jonathan King:
Yeah. Just to anticipate a question on this, competing revisions, however, can only continue during the length of the parent award.

Melissa Riddle:

Parent award.

Jonathan King:
Though in some cases there may be people who have a compelling scientific case to make a one-year competing revision, and they cannot make the second year because it would go past the end of the parent. In that case, it's perfectly fine to ask for the single-year funding. But, in fact, you have to do that because if the end date goes beyond the parent award, it will not be accepted by the system.

Chandra:
Okay. I'm just going to say a statement, and you tell me if I'm correct. The parent award has to have been awarded prior to submitting the revision application.

Melissa Riddle:
Exactly. That is correct.

Jonathan King:
That is correct. That's unfortunate, because in some cases, it is the case that it's all but certain an award will be made, but the system cannot process a competing revision before there's an award in the system.

Melissa Riddle:
Right. And that information is detailed at that URL on page -- slide number 28.

Jonathan King:
Right.

Chandra:
Okay? For the -- this person wrote, "For the R21s," -- I think it applies to all the [unintelligible] -- "is the focus always on patient-oriented outcomes, for example, medication adherence? Or could the behavior change also be focused on provider behaviors, for example, medication ordering behaviors?" It's absolutely -- if you're interested in provider behavior --

Melissa Riddle:
They're humans.

Chandra:
Yep. [laughs]

Jonathan King:
There are [inaudible] that have been done specifically on provider behavior.

Female Speaker:
Yep.

Jonathan King:

So, for example, I was department official for a large, randomized trial among providers that was an attempt to basically make them prescribe antibiotics more appropriately, which is to say, in this particular case, for the common cold, not to prescribe the antibiotic.

Chandra:
[laughs]

Jonathan King:
Colds are caused by viruses, and antibiotics do not work on viruses. There are indications in some cases where people, for example, are subject to secondary infections, where antibiotics are appropriate. But 99 percent of the time, the answer is no. And that was a perfectly fine clinical trial that had a DSMB and had everything else going for it, and was definitely on provider behavior, in this case actually prescription behavior, but ordering or other sorts of things would definitely be within realm.

Again, the point there would be to make sure that the target process would, in the providers that you're intervening on, is a match for what we have in SOBC, and what have you. But I can actually imagine situations where that would happen.

Chandra:
Yeah.

Jonathan King:
Yeah.

Melissa Riddle:
Social processes.

Chandra:
Yeah. Okay. I am not seeing any additional questions. There's a couple -- we have a few more minutes, if anyone wants to submit a last-minute question right now. I'll just say I'm sorry, when I forwarded a reminder to you all earlier this week, I included my own reminder.

[end of transcript]