WEBVTT

1 00:00:00.000 --> 00:00:04.410Henry Xiang: This information session and Q&A 2 00:00:04.920 --> 00:00:12.230 Henry Xiang: about the CCTS 2023 Pilot RFA. 3 00:00:12.310 --> 00:00:14.020 Henry Xiang: You can 4 00:00:14.180 --> 00:00:15.780 Henry Xiang: move on to the next slide, 5 00:00:17.030 --> 00:00:18.630 Henry Xiang: Jasmine 6 00:00:18.640 --> 00:00:40.330 Henry Xiang: Okay, so currently, I'm the Director of CCTS Pilot Translational and Clinical Studies Program. I'm actually here at the Nationwide Children's Hospital. We have our pilot program manager, Jasmine. She's at the OSU main campus. 7 00:00:40.810 --> 00:00:41.570 Henry Xiang: Next (slide). 8 00:00:43.580 --> 00:00:54.230 Henry Xiang: Okay, I want to emphasize the applicants who plan to submit a project to this g 00:00:54.250 --> 00:00:56.930 Henry Xiang: current RFA, must pay close 10 00:00:57.050 --> 00:01:02.209 Henry Xiang: attention to this funding priority. Actually, the is a requirement. 11 00:01:02.250 --> 00:01:06.690 Henry Xiang: The NIH CTSA Funding Opportunity Announcement,

12 00:01:06.720 --> 00:01:21.739 Henry Xiang: PAR. 21-2-99, stipulates that pilot studies funded through the CTSA must be focused on translational science, that is. understanding that scientific and operational principles 13 00:01:21.740 --> 00:01:44.290 Henry Xiang: underlying a step of translational process with the goal of developing generalizable solutions to accelerate translational research studies may focus on a specific clinical and translational research area to develop or test that translational science. But however, 14 00:01:44.790 --> 00:02:08.450 Henry Xiang: your proposed study must focus on transnational science versus transnational research. People may ask, "Okay, what's translational science? And what's translational research?". I have to tell you, this is an evolving concept. However, because the 15 00:02:09.310 --> 00:02:22.089 Henry Xiang: OSU CCTS receives funding through the CTSA, we have to follow the NIH NCATS funding requirement. 16 00:02:22.110 --> 00:02:23.790 Henry Xiang: Next slide. 17 00:02:25.340 --> 00:02:44.280 Henry Xiang: There are some general ideas about translational science principles. I will share in the next slides several literature and online resource for you to read. But, generally speaking, you know, translational science wants to (adhere to these principals). 18 00:02:44.480 --> 00:02:53.300 Henry Xiang: Here is the 8 general principles. The first one must prioritize initiatives that address unmet needs. 19 00:02:53.530 --> 00:03:20.869 Henry Xiang: Second, produce cross cutting solutions for common and persistent challenges in transnational research. (3) Emphasize creativity and innovation. (4) Leverage cross-disciplinary team science. (5) Enhance the efficiency and the speed of translational

research. (6)Utilize boundary-crossing partnerships to advance translation. 20 00:03:20.940 --> 00:03:25.030 Henry Xiang: (7) Use bold and rigorous research approaches. 21 00:03:25.120 --> 00:03:44.040 Henry Xiang: (8) Prioritize diversity, equity, inclusion, and accessibility. Out of these 8 scientific Translational Science Principles, I want you, actually, to pay closer attention to the second one, 22 00:03:44.360 --> 00:03:50.260 Henry Xiang: that is cross-cutting solutions for common and persistent challenges. 23 00:03:50.300 --> 00:03:51.520 Henry Xiang: Next (slide), please. 24 00:03:54.620 --> 00:04:20.430 Henry Xiang: So, translational research, basically, you know, historically, translational research is defined as the effort to traverse specific steps of the translational process for a particular disease and target. From this you can say, we have T0, which focused on basic science. 25 00:04:20.430 --> 00:04:33.839 Henry Xiang: T1 translational to humans and T2 translational to patients and T3 translational to practice and T4 translational to communities. However, you know, in our 26 00:04:33.910 --> 00:04:58.899 Henry Xiang: previous RFA, or previous concept of translational research, we do not have, eh, we do not emphasize or prioritize that projects must focus on translational science versus translational research. But the concept here is we want you to create generalizable results across 27 00:04:58.900 --> 00:05:16.759 Henry Xiang: different disease or, eh, or spectrum of these stages of disease. So in a way, your research findings result should be applicable to other conditions, or maybe different stages.

28 00:05:17.080 --> 00:05:18.290 Henry Xiang: Next (slide), please. 29 00:05:20.310 --> 00:05:36.170 Henry Xiang: Eh, Transnational Science Resources. This is a paper published by a CTSA and NIH employee, 30 00:05:36.180 --> 00:05:55.190 Henry Xiang: Dr. Faupel-Badger. You should go to the PubMED download for that publication. It is well written and and fun to read. And you will learn a lot from it. 31 00:05:55.190 --> 00:06:06.200 Henry Xiang: Also there is the National Center For Advancing Translational Science. They provide these rich resources in terms of the 32 00:06:06.230 --> 00:06:23.510 Henry Xiang: transnational science principles, issues in translation, transforming translational science, and translational science resources. You know, before you apply, I strongly encourage you to download that paper. 33 00:06:23.670 --> 00:06:31.880 Henry Xiang: but I also recommend that you read all the materials on the National Center for Advanced Transnational Science Webpage. 34 00:06:34.070 --> 00:06:35.750 Henry Xiang: Okay, next (slide). 35 00:06:36.970 --> 00:07:05.669 Henry Xiang: These are the funding priorities. This request for applications is designed to support proposals that advance transnational science. The goal of the PTC pilot research funding award is to fund highly meritorious research for the development of preliminary data, to enable researchers to be competitive, in applying for extramural funding. 36 00:07:05.670 --> 00:07:30.260 Henry Xiang: So two kinds of, eh, two things you need to keep in mind,

say, you know, one thing I already said is, we emphasize our priorities, translational assigns project. And, second, since you want to keep in mind when you did design your study, we don't want you to just stop here after you receive the funding conduct, study and the publish 37 00:07:30.260 --> 00:07:56.450 Henry Xiang: publish a paper. We actually want you to design a study, you say, after you finish the 12 months of this project, you will go, you will submit for extramural grant to the Federal grant, eh, Federal funding agencies or other State or other funding agents to get extramural funding to continue your research. 38 00:07:57.290 --> 00:07:59.110 Henry Xiang: Next (slide), please. 39 00:08:00.810 --> 00:08:14.920 Henry Xiang: Eh, we intentionally designed this RFA, where we will support the pilot programs in two stages. Some background information here. So, 40 00:08:15.310 --> 00:08:30.339 Henry Xiang: the CCTS receive funding from NIH, I think, is starting in 2008. In this last year, we submit a renewal to 41 00:08:30.490 --> 00:08:33.890 Henry Xiang: to continue the support to 42 00:08:34.360 --> 00:08:35.390 Henry Xiang: the 43 00:08:35.750 --> 00:08:39.049 Henry Xiang: CCTS and the Pilot project, but 44 00:08:39.669 --> 00:08:58.170 Henry Xiang: the NIH changed their funding mechanism. We are now in a new stage. Luckily, you know. It's a great news for us. The CCTS renew received seven years of funding starting on August, correction 45 00:08:58.620 --> 00:09:00.759 Henry Xiang: September of this year.

46 00:09:01.420 --> 00:09:12.299 Henry Xiang: So you can say we expect to continue, eh, continue to support pilot projects 47 00:09:12.300 --> 00:09:32.520 Henry Xiang: through the rest of the funding period, which is another 7 years. In this first stage we want to provide pilot grant funding in the amount of 25k to 50k over the total period of support. 48 00:09:32.520 --> 00:09:49.279 Henry Xiang: That's we call this stage one. The priority is to remove barriers for investigators to conduct their study translational science. So we do not require that the department or the college to have a match in funds. 49 00:09:49.410 --> 00:09:51.970 Henry Xiang: Eh, out of those 50 00:09:52.410 --> 00:10:19.870 Henry Xiang: selected pilot projects, we will then, choose, like 50% of completed the stage one pilot projects and then using the CCTS administr- , eh, administrative support and team science training to help the research team to do a like a validation 51 00:10:20.140 --> 00:10:28.279 Henry Xiang: stage. To help them to test the validation of the team science studies to enable the 52  $00:10:28.280 \longrightarrow 00:10:57.779$ Henry Xiang: advancement of the most impactful and the generalizable approaches. I want to emphasize here, even though the CCTS will provided administrative support and also have an expert who help your team to implement that. But, however, you know, we are still in the discussion, you know, of how we will support you in terms of 53 00:10:57.780 --> 00:11:03.860 Henry Xiang: whether we will provide financial support at this moment. We have no plan to pro-54 00:11:03.910 --> 00:11:13.340

Henry Xiang: provide additional pilot funding to those selected pilot projects at the second stage. 55 00:11:13.830 --> 00:11:15.400 Henry Xiang: Next slide, please. 56 00:11:17.270 --> 00:11:28.110 Henry Xiang: Okay, I will stop here and we will let Jasmine take it over to talk about the rest of the important information you need to know. 57 00:11:29.090 --> 00:11:44.890 Jasmine Neal: Yes, and I just wanna let everyone know that we will be posting these slides on the RFA web page on the CCTS website. So you'll have access to these slides as well as their accompanying links. So you can look at this information again. 58 00:11:45.650 --> 00:11:58.430 Jasmine Neal: So eligibility criteria for this grant is applicants must have a status of principal investigator, as defined by OSA and a nationwide Children's Hospital. 59 00:11:58.590 --> 00:12:09.260 Applicants may not have received a CCTS Pilot Grant within 24 months of this application's deadline, which is October thirtieth. 60 00:12:09.590 --> 00:12:23.039 Jasmine Neal: As Dr. Xiang has discussed projects must be translational science, and we really want these projects to be focused on preliminary research 61 00:12:23.200 --> 00:12:32.039 Jasmine Neal: that could be completed within one year and has a high probability of obtaining extramural funding 62 00:12:32.500 --> 00:12:43.600 Jasmine Neal: with a focus on the development of new concepts, methods, technologies, and research practices that drive translational science. 63 00:12:43.940 --> 00:12:57.280

Jasmine Neal: Proposals should clearly identify challenges or barriers and propose the development of a solution or process that can be tested within the pilot project. 64 00:12:59.400 --> 00:13:09.019 Jasmine Neal: This is the 2023 pilot Grant application timeline. So we released this RFA on the 29 of September. 65 00:13:09.170 --> 00:13:21.890 Jasmine Neal: Applicants must conduct their regulatory consults with April Green, our CCTS Regulatory Officer by Thursday, October 19, 2023. 66 00:13:22.240 --> 00:13:38.430 Jasmine Neal: Send a mandatory budget review on, to- and there will be more information in the coming slides about how to do this, these processes. But the mandatory Budget Review is due by October 20, 2023. 67 00:13:38.450 --> 00:13:44.400 Jasmine Neal: That is Friday next week. As well as the mandatory Data Science Review. 68 00:13:44.620 --> 00:13:49.899 Jasmine Neal: The application due date is Monday, October 30, 2023. 69 00:13:50.360 --> 00:14:01.430 Jasmine Neal: And then from there, just to give you guys an idea of what the review process timeline is, we will conduct reviews on November 28-29, 2023. 70 00:14:01.630 --> 00:14:12.810 Jasmine Neal: Our executive committee will determine approvals on November 30, and notices of award will go out on December 4, 2023. 71  $00:14:14.470 \longrightarrow 00:14:22.849$ Jasmine Neal: And then NCATS prior approval documents, for those who are selected for funding, will be due December 15, 2023. 72 00:14:23.030 --> 00:14:37.759 Jasmine Neal: The earliest start date for projects will be somewhere between January and February 2024. There is an asterisk there because

projects cannot begin until NCATS prior approval has been received. 73 00:14:38.890 --> 00:14:40.050 Jasmine Neal: Okay. 74 00:14:40.110 --> 00:14:47.649 Jasmine Neal: So the Regulatory Consult. To schedule that meeting you need to contact April green. 75 00:14:48.100 --> 00:15:12.270 Jasmine Neal: and in your contact email, you need to include a few sentences giving an overview of your project to her. And if you could please subject line your email "Pilot Regulatory Consult" just to make sure that it's indicated as a high priority need, and that she addresses that email quickly. That will help her in identifying your email and your needs. 76 00:15:13.540 --> 00:15:30.739 Jasmine Neal: What to expect from your meeting with April. So you will discuss your project and determine your NCATS category for the research that you are conducting, and she will provide you with documents related to the NCATS prior approval, submission 77 00:15:30.740 --> 00:15:50.450 Jasmine Neal: to help you prepare and get get documents gathered for in the case that you are selected for funding, because that's a really quick turnover. So we give you your notice of award on December fourth, and that full submission is December fifteenth. So you want to begin to gather your documents together before then. 78 00:15:50.890 - > 00:15:59.749Jasmine Neal: If you choose. So you can get NCATS prior approval as soon as possible, and begin your work as soon as possible. 79 00:16:02.790 --> 00:16:12.540 Jasmine Neal: The Budget Review. So there is a budget form and instructions in the REDCap application. You will need to download that form, 80 00:16:12.740 --> 00:16:22.550 Jasmine Neal: complete it and send it to our Financial Operations Analyst, Todd Huffman. And his contact information is included in

here.

81 00:16:22.720 --> 00:16:30.740 Jasmine Neal: Please Cc me on that email and subject line "Pilot Budget Review". So we can tend to that quickly. 82 00:16:30.790 --> 00:16:41.610 Jasmine Neal: If there are any issues with your budget, Todd will reach out to you and we'll kind of discuss maybe some things that need to be reviewed. 83 00:16:41.740 --> 00:16:59.070 Jasmine Neal: We just wanna make sure that your budget is sound, that things like: fringe benefits; if you have a GRA or a graduate research assistant; any external collaborators. There's a lot of administrative 84 00:16:59.290 --> 00:17:15.530 Jasmine Neal: back work that goes to facilitating some of those things and since this is a 12 month project. We wanna make sure that things are in a way that they can be completed on time and you can really get started on your work, quickly. 85 00:17:16.369 --> 00:17:28.189 Jasmine Neal: Likewise for the Data Science Review. It's a one page summary instructions are included in the Red Cap application and you will be emailing that to me for me to review 86 00:17:28.210 --> 00:17:30.989 Jasmine Neal: by October 20, 2023. 87 00:17:34.260 --> 00:17:44.579 Jasmine Neal: The application itself: So it consists of a research strategy, which is 5 pages, a maximum of 5 pages, not including references. 88 00:17:44.730 --> 00:17:52.270 Jasmine Neal: a one-page data, science summary. a one-page lay summary project, milestones and timeline. 89 00:17:52.510 --> 00:17:59.120 Jasmine Neal: As well as bio sketches for all key personnel as well as

any other support. 90 00:17:59.140 --> 00:18:04.800 Jasmine Neal: A budget, budget justification and letters of support. 91 00:18:04.820 --> 00:18:12.430 Jasmine Neal: So all applications need to have a letter of support from their department chair. If your project 92 00:18:12.770 --> 00:18:22.070 Jasmine Neal: has human subjects or is engaging with the community, you need to have a letter of support from a patient or community stakeholder as well. 93 00:18:24.920 --> 00:18:42.329 Jasmine Neal: Alrighty, we'll open the floor for some Q&A. If you could. Please raise your hand just in case we have multiple questions at the same time. Or tap your question into the chat box, and I will read it out loud. But I'll open the floor for questions. 94 00:18:44.530 --> 00:18:46.010 Jasmine Neal: Let's see here. 95 00:18:48.150 --> 00:18:56.250 Jasmine Neal: So I do have a question in the chat box asking our animal based studies, allowed? The answer to that question is, yes. 96 00:18:58.860 --> 00:19:00.579 Jasmine Neal: Any other questions? 97 00:19:06.560 --> 00:19:21.039 Jasmine Neal: Let's see here. I see a last name I'm sorry I don't want butcher it, but I see your hand is up" 98 00:19:21.120 --> 00:19:24.750 coutellier.8: So I'm the one asking the question about animal studies. In that case, how does the NCATS Apply? Because my understanding is that NCATS is mostly for human subjects. 99 00:19:24.850 --> 00:19:26.750

coutellier.8: I might be wrong, so 100 00:19:26.900 --> 00:19:51.200 Jasmine Neal: That would be a great question for our regulatory officer, but I know that it is indeed allowed, and she can help you with navigating any questions with NCATS. We have lots of questions popping up in the chat box now. So "does an applicant have to be faculty? Are research scientists with PI status eligible?" Yes, is the answer to that question. 101 00:19:51.860 --> 00:19:55.790 Jasmine Neal: "Do you require any preliminary data for the submission?" Henry, can I have you answer that question? 102 00:19:55.820 --> 00:20:09.769 Henry Xiang: You do not need a primary data for the submission, you know. But, however, if you have preliminary data that'd be great. 103 00:20:11.060 --> 00:20:18.699 Jasmine Neal: And another question we have in the chat box is, "How many reviewers would assess the application?". 104 00:20:18.840 --> 00:20:27.740 Jasmine Neal: So we'll have at least one external reviewer as well as a community reviewer, and we may have an internal reviewer as well. 105 00:20:29.040 --> 00:20:43.849 Jasmine Neal: Let's see here. "Could you explain a little more about the patient letter needed?" So A letter of support from a patient is where a patient or community stakeholder 106 00:20:43.850 --> 00:21:06.519 Jasmine Neal: is familiar with the work that you're doing, and is in support of it, and is in support of the way that you are conducting that research. So really, what we're looking for is that the question that you're asking is relevant to the community and the way that you're going about investigating that question is supported and aligned with the community. 107 00:21:08.580 --> 00:21:12.720

## Jasmine Neal: Let's see here, next question... 108 00:21:13.990 --> 00:21:19.780 Jasmine Neal: Let's see, "How many awards do you anticipate will be given?". Henry, I can let you answer that question, but I believe it's 4 to 5. 109 00:21:20.300 --> 00:21:33.200 Henry Xiang: Yeah. So Karen, you know our budget will allow 4 to 5 110 00:21:33.210 --> 00:21:53.669 Henry Xiang: you know, awards, but also there's a possibility if some of the applicants do not use do not have a budget up to 50,000, we may add one more. So, it's really, you know I want emphasize here that, 111 00:21:53.670 --> 00:22:06.600 Henry Xiang: you know, put a reasonable budget to finish your project. So, that will allow us to fund as many as pilot projects. 4 to 5 that's what we are looking for. 112 00:22:09.040 --> 00:22:18.739 Jasmine Neal: Okay, I have another question here related to the data science summary? Someone is wanting to know "Will it be similar to an abstract?" 113 00:22:18.890 --> 00:22:31.589 Jasmine Neal: The answer to that question is, yes, in the application there are very particular instructions about how to complete that summary, and what things need to be addressed in it. 114 00:22:32.910 --> 00:22:39.390 Jasmine Neal: I have another question, "Can we have a co-pi?" The answer to that is, yes. 115 00:22:39.630 --> 00:22:52.900 Henry Xiang: But yeah, here the other question is multiple pis. And now yes, we allow co-pi, co-investigator multiple PIs. But keeping keeping in mind, 116 00:22:52.950 --> 00:23:00.619 Henry Xiang: in terms of budget, we have a requirement of the PI's

total budget cannot exceed 117 00:23:01.070 --> 00:23:15.280 Henry Xiang: 5% of the total budget. We really want you to use the money to get the personnel to finish the project. So 5% of faculty salaries, that's the cap. 118 00:23:18.120 --> 00:23:22.849 Jasmine Neal: And we have one more question here. Well, we've got more questions popping up. 119 00:23:23.110 --> 00:23:32.679 Jasmine Neal: "So it seems like once you have a meeting with April green, we will know whether we are allowed to submit a full proposal or not. Is that correct?". 120 00:23:32.950 --> 00:23:45.790 Jasmine Neal: The regulatory consult with April will allow her to identify any major needs that we might have in submitting your NCATS prior approval. 121 00:23:45.790 --> 00:24:11.950 Jasmine Neal: So it's not an approval for an application. There's no pre-application, no letter of an intent. If there is anything starkly concerning about your about your project that she identifies during your meeting, you guys can discuss it. You can also discuss it with me as well as Henry, and maybe there's something that we can, we can help you kind of 122 00:24:12.090 --> 00:24:23.530 Jasmine Neal: restructure, or come to your question from a different angle. But no, the regulatory console is not a approval for you to submit a full application. 123 00:24:25.080 --> 00:24:28.889 Jasmine Neal: Let's see, here. 124 00:24:30.190 --> 00:24:39.290 Jasmine Neal: "Is it required to have a co-pi? Can you submit, can you-, can the pi submit a grant without a co-pi?" Yes.

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00:24:40.760 --> 00:24:48.360 Henry Xiang: I can. I can answer that next question. "Can the PI have a 0% of effort or paid effort?" You know, 126 00:24:48.360 --> 00:25:13.880 Henry Xiang: it depends on your university's policy, or the here at nationwide children's hospital, we have a policy that you must have some effort on that, whether that's paid or not paid. You got to, you know, have a good justification, your budget justification, but you must, the PI must have some effort on the project. 127 00:25:13.880 --> 00:25:27.130 Henry Xiang: So, you know, the SPO or the Institute can match that project either is paid or unpaid that's, that's up to you to talk with your SPO. 128 00:25:34.400 --> 00:25:36.580 Henry Xiang: Do we have other... 129 00:25:38.590 --> 00:25:41.660 Henry Xiang: other questions here? Okay. 130 00:25:44.770 --> 00:26:09.470 Jasmine Neal: Well, if you develop any questions, later, or as you go through the application, please do not hesitate to email me. I am happy to answer any questions you have. You can also give me a call as well. Again, these slides will be posted on the the CCTS pilot programs page. So you can refer back to them as well as their associated links. 131 00:26:09.700 --> 00:26:16.829 Jasmine Neal: Thank you. Everyone very much for your time today. And again, my name is Jasmine Neal, and I'm the pilot programs manager. 132 00:26:17.650 --> 00:26:37.640 Henry Xiang: Oh, there's a question here, Jasmine. "If we request a 25k budget, anywhere less than 50. So we don't have to match up 50. Sorry for the last minute question". Yeah, so like I said that the budget ranges from 25K to 50K. You don't have to request up to-, you don't have to say I must use the 50K. 133 00:26:37.740 --> 00:26:42.219

Henry Xiang: So, it's between 25K to 50K. 134 00:26:42.890 --> 00:26:53.099 Henry Xiang: Jasmine, can you share the people here how soon you will post Powerpoint 135 00:26:53.300 --> 00:26:54.170 Henry Xiang: slides. 136 00:26:54.330 --> 00:26:57.160 Jasmine Neal: Yeah, absolutely. It could take... 137 00:26:57.200 --> 00:27:04.390 Jasmine Neal: maybe...by Wednesday morning at latest. 138 00:27:05.820 --> 00:27:06.600 Henry Xiang: Okay. 139 00:27:06.700 --> 00:27:08.360 Jasmine Neal: Wednesday morning. Yes. 140 00:27:13.450 --> 00:27:39.920 Henry Xiang: Okay. That's end our the the first RFA Information session and Q&A session here we really appreciate everybody's attention, and the time from your busy schedule to attend this, and we wish you good luck. If you have any guestions, please feel free to send me an email or send an email to Jasmine. 141 00:27:40.350 --> 00:27:41.230 Henry Xiang: Thank you. 142 00:27:41.480 --> 00:27:42.910 Jasmine Neal: Thank you. Everyone. 143 00:27:43.800 --> 00:27:44.500 Yeah.