WEBVTT

1

00:00:00.000 --> 00:00:00.900

Reven.

2

00:00:09.150 --> 00:00:12.110

Chuck Montague: There we go, authority on the on that tough questions.

3

00:00:14.600 --> 00:00:15.380

Penny F. Ford-Carleton: right?

4

00:00:24.350 --> 00:00:29.540

Steve Schachter: So on this drawing is which Hub is for which Hemi circle here.

5

00:00:30.730 --> 00:00:33.740

Chuck Montague: Good question.

6

00:00:35.960 --> 00:00:36.590

Chuck Montague: Good!

7

00:00:37.880 --> 00:00:39.000

Steve Schachter: And why?

8

00:00:40.680 --> 00:00:43.220

Chuck Montague: Oh, I have a definite answer. But

9

00:00:43.300 --> 00:00:51.290

Chuck Montague: since we might be recording, or since Ni is on. we are recording

10

00:00:51.810 --> 00:00:56.400

Penny F. Ford-Carleton: welcome, everyone that's coming in. We'll start in just a couple of moments

11

00:01:39.640 --> 00:01:45.870

Penny F. Ford-Carleton: again. Welcome. I know folks is still coming in, so we'll just wait another minute or so.

12

00:02:06.680 --> 00:02:10.530

Chuck Montague: You still ride, Steve. You still bike. Oh.

13

00:02:11.420 --> 00:02:13.360

Chuck Montague: I do. I have my bike down here.

14

00:02:13.490 --> 00:02:14.990

Chuck Montague: So, bye.

15

00:02:16.920 --> 00:02:24.110

Chuck Montague: Yeah, I we'll talk about that some other time. But you won't be recording.

16

00:02:25.910 --> 00:02:29.000

Penny F. Ford-Carleton: So why don't we get started?

17

00:02:29.070 --> 00:02:33.040

Penny F. Ford-Carleton: Welcome everyone to this informational Webinar

18

00:02:33.050 --> 00:02:44.500

Penny F. Ford-Carleton: on the sinta n th announcement for the spring 2,023 award competition. As you all know, this is supported by the Nih blueprint med tech program.

19

00:02:44.690 --> 00:03:01.860

Penny F. Ford-Carleton: And this is really designed for all of you. We want this to be very interactive, so we can be responsive to your questions and optimize your your chance of success. Now we're joined, and i'll introduce you in a moment by leadership from both hubs, sent him

20

00:03:01.950 --> 00:03:18.630

Penny F. Ford-Carleton: the P. I. Of into which is center for innovative neuro tech advancement is Steve Shackter, and he's on the line. Debbie Lee from Santa is also on the line Neuro Tech Harbor. We have Chuck Montague, and then we also have Nih leadership, and

21

00:03:18.630 --> 00:03:24.080

Penny F. Ford-Carleton: I believe Mike Wilson is on the line with his colleagues. I can't see everyone at this moment.

22

00:03:24.520 --> 00:03:33.890

Penny F. Ford-Carleton: Just a few logistical comments to protect your anonymity. We have blinded all of your photos and your names. So

23

00:03:33.890 --> 00:04:03.710

Penny F. Ford-Carleton: what we'd like to do with your questions is, go into the Q. A. The questions and answer at the bottom of the screen. Select anonymity, and then those questions will be displayed to us. If your questions are generic and others would benefit from those questions, we will read them and then respond. If it's specific to your proposal, because we know that some of you are on the line to ask questions about resubmission. We Won't. Then read those particular questions.

24

00:04:04.370 --> 00:04:16.700

Penny F. Ford-Carleton: Then one other logistical comment is, If you choose to do so, please enable the captions at the at the bottom of the screen.

25

00:04:17.120 --> 00:04:20.769

Penny F. Ford-Carleton: So with that said, Why, Don't, we go on to the next slide.

26

00:04:25.280 --> 00:04:26.000

Penny F. Ford-Carleton: Great.

27

00:04:26.160 --> 00:04:39.600

Penny F. Ford-Carleton: So this is program overview. The blueprint med tech program has funded these 2 incubator hubs that I mentioned for 5 years. Sinta is the program within semit based in Boston.

28

00:04:39.650 --> 00:04:42.480

Penny F. Ford-Carleton: Steve Shackter on the line is the

29

00:04:42.550 --> 00:04:50.960

Penny F. Ford-Carleton: while a Bernado who's bald and is the copi. He couldn't join us today, but he works obviously closer with this hub

30

00:04:51.350 --> 00:05:07.640

Penny F. Ford-Carleton: Bureau Tech Harbor is a partnership between Johns Hopkins University and Howard University, with 3 for a Sara as contact the I. She is unable to join us today, but Chuck, not to queue, is is on the line.

31

00:05:07.880 --> 00:05:18.460

Penny F. Ford-Carleton: So the mission of this program is to accelerate the development of emerging groundbreaking technologies into first in human studies.

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00:05:18.680 --> 00:05:28.440

Penny F. Ford-Carleton: and to support the projects along the path to commercially viable, clinically focused solutions for disorders involving the nervous system.

33

00:05:29.020 --> 00:05:37.780

Penny F. Ford-Carleton: So this is designed to catalyze translation. We get a novel emerging i'm breaking technologies from early stage development

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00:05:37.820 --> 00:05:50.860

Penny F. Ford-Carleton: to a human grade prototype ready for first in human testing within 4 years. So each element of that sentence is important. We'll come back to that during the during the presentation.

35

00:05:50.960 --> 00:05:52.860

Penny F. Ford-Carleton: So next slide. Please

36

00:05:58.040 --> 00:06:02.160

Jessica Sheeran: hold on one moment, please. I'm having trouble advancing.

37

00:06:02.990 --> 00:06:10.260

Penny F. Ford-Carleton: Not an issue. So what you'll see on the next slide is the cycle of innovation.

38

00:06:10.800 --> 00:06:17.550

Penny F. Ford-Carleton: and, as you probably all know, there are 10 things, one from the idea

39

00:06:17.590 --> 00:06:20.100

Penny F. Ford-Carleton: through the

40

00:06:20.200 --> 00:06:25.630

Penny F. Ford-Carleton: the up through a proof of concept. There it goes. Thank you. So clinical need to idea

41

00:06:25.990 --> 00:06:32.250

Penny F. Ford-Carleton: proof of concept for feasibility, proof of value, initial clinical trials, and so forth.

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00:06:32.500 --> 00:06:47.550

Penny F. Ford-Carleton: The sweet spot for our particular program is in green. That's from proof of concept to proof of feasibility and proof of value prior to the additional clinical trials. So we would be supporting projects

43

00:06:47.740 --> 00:06:52.990

Penny F. Ford-Carleton: to develop the human brain prototype. So it's ready for first human testing

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00:06:53.590 --> 00:06:54.740

Penny F. Ford-Carleton: next. So

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00:06:56.650 --> 00:07:07.700

Penny F. Ford-Carleton: so just details from the funding opportunity. Probably all this in the solicitation. and it can be found at blueprint neurotect org.

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00:07:08.050 --> 00:07:16.660

Penny F. Ford-Carleton: So awards from the hubs will really exceed 500,000 in direct costs per year for a period of up to 4 years.

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00:07:17.100 --> 00:07:25.340

Penny F. Ford-Carleton: What's unique about this program? One of the unique features is that it's not just funding. In addition to monetary support

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00:07:25.600 --> 00:07:29.080

Penny F. Ford-Carleton: projects receive ongoing specialized support

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00:07:29.090 --> 00:07:36.150

Penny F. Ford-Carleton: from executive mentors with decades of experience in developing and commercializing neuro tech devices.

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00:07:36.640 --> 00:07:55.880

Penny F. Ford-Carleton: So awardies will work with their mentors for several hours each week, focusing on all aspects of development, business, regulatory, clinical, and technical factors, all the challenges that may impede commercialization. There will be a time commitment, but great value

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00:07:55.880 --> 00:08:00.360

Penny F. Ford-Carleton: relative to this mentorship. So on the next slide

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00:08:02.360 --> 00:08:06.230

Penny F. Ford-Carleton: there are resources that we will also

53

00:08:06.310 --> 00:08:20.050

Penny F. Ford-Carleton: make available to different teams. So we have the mentoring. But we also have these resources to plan and support prototype development, team building need assessment and other early translational activities.

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00:08:20.290 --> 00:08:33.049

Penny F. Ford-Carleton: We have an extensive network of consultants, both within the hubs and within a an age for these elements mentioned to your design, regulatory reimbursement, IP.

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00:08:33.610 --> 00:08:49.680

Penny F. Ford-Carleton: There are other resources listed on the blueprint med tech website, and this link is also in the solicitation, and we will be posting these slides on that link that i'll show you in just a bit, so these resources will be available to you

56

00:08:49.720 --> 00:08:52.550

Penny F. Ford-Carleton: upon successful completion.

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00:08:52.660 --> 00:08:54.250

Penny F. Ford-Carleton: This

58

00:08:54.310 --> 00:08:56.060

Penny F. Ford-Carleton: award period

59

00:08:56.210 --> 00:09:09.320

Penny F. Ford-Carleton: team should have secured non-governmental funding, or be ready for entry into companion solicitations from Nih, and these are 2 solicitations that support translational activity.

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00:09:09.700 --> 00:09:11.170

Penny F. Ford-Carleton: So next slide

61

00:09:13.530 --> 00:09:31.140

Penny F. Ford-Carleton: this details those potential resources I know it's bit busy, so don't expect anyone to be able to read all of this, but you could see the link the blueprint mid tech resources that's available with this particular slide on your website.

62

00:09:31.280 --> 00:09:42.490

Penny F. Ford-Carleton: But you could see there are resources that will be provided by the hubs. There are other resources that are provided by the Nih blueprint Med tech program.

63

00:09:42.510 --> 00:09:52.600

Penny F. Ford-Carleton: They include design, prototyping, risk analysis. bench and safety testing bio compatibility and animal studies.

64

00:09:52.940 --> 00:09:57.010

Penny F. Ford-Carleton: Pre-clinical studies. We don't support clinical studies.

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00:09:57.820 --> 00:10:01.800

Penny F. Ford-Carleton: Neuroethics is an important component of our program.

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00:10:01.910 --> 00:10:08.920

Penny F. Ford-Carleton: and then we have business development, resources, entrepreneurship, business development, commercialization

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00:10:09.420 --> 00:10:14.010

Penny F. Ford-Carleton: and regulatory compliance quality systems and legal.

68

00:10:14.020 --> 00:10:21.460

Penny F. Ford-Carleton: which which could be challenging for some groups that are new to this deal. So we have those those resources.

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00:10:21.780 --> 00:10:23.520

Penny F. Ford-Carleton: So on the next slide

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00:10:25.810 --> 00:10:34.370

Penny F. Ford-Carleton: it's important. This is another unique feature of this program. There are 11 participating centers and institutes

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00:10:34.400 --> 00:10:44.700

Penny F. Ford-Carleton: that are supporting this program. So there is a very diverse range of interests relative to disorders of the nervous system.

72

00:10:45.020 --> 00:10:56.460

Penny F. Ford-Carleton: It's very important that applicants must focus on a disorder of the nervous system in an area of priority interest to one of these participating centers.

73

00:10:56.690 --> 00:11:03.790

Penny F. Ford-Carleton: and what we expect that you will do is go on to this website. Look at the priority areas

74

00:11:04.180 --> 00:11:15.860

Penny F. Ford-Carleton: and see if your application is aligned with these missions. If it is not aligned with the missions that are scribed down the website, then you would not be eligible for funding.

75

00:11:16.300 --> 00:11:27.290

Penny F. Ford-Carleton: Now we'll be responsive to. We have a a link to our hubs that if you have questions about your application, you can forward those questions to us

76

00:11:27.290 --> 00:11:43.070

Penny F. Ford-Carleton: if you have questions about mission fit. Those are the only questions that really the to program offices can help you with. We can be responsive to the others, so it's important to be familiar with with which is to to support this initiative.

77

00:11:43.570 --> 00:11:45.240

Penny F. Ford-Carleton: So on the next slide

78

00:11:47.160 --> 00:11:57.310

Penny F. Ford-Carleton: relative to eligibility, pis for academic institutions, industry, or nonprofit organizations are all invited to apply

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00:11:57.930 --> 00:12:09.890

Penny F. Ford-Carleton: Academic pi's must hold a faculty appointment at an institution of higher education or medical center pis from industry or non academic nonprofits will not

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00:12:10.130 --> 00:12:13.300

Penny F. Ford-Carleton: be required to have an important faculty appointment.

81

00:12:13.560 --> 00:12:17.280

Penny F. Ford-Carleton: And we're encouraging applications for women

82

00:12:17.300 --> 00:12:22.080

Penny F. Ford-Carleton: under represent racial and ethnic groups integrals with disability

83

00:12:22.360 --> 00:12:30.130

Penny F. Ford-Carleton: and also under resource community. I can see there are 3 questions here. So why Don't? I pause.

84

00:12:30.290 --> 00:12:33.910

Chuck Montague: Nothing's relevant that they're They're just comments.

85

00:12:34.010 --> 00:12:40.960

Penny F. Ford-Carleton: Okay, good. So thanks, okay. Next slide, please.

86

00:12:42.860 --> 00:12:49.790

Penny F. Ford-Carleton: So this is the review process. First applicants submit what we call pre proposal.

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00:12:50.180 --> 00:12:57.860

Penny F. Ford-Carleton: and that undergoes review by the leadership from Sinton or a tech harbor on the Nih Scientific staff.

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00:12:58.500 --> 00:13:17.370

Penny F. Ford-Carleton: And this proposal is a relatively simplified process. It's an online application. It's equivalent to about 4 pages, and i'll go through some of the sections that you'll be looking to complete, and each section has a board limits.

89

00:13:17.370 --> 00:13:25.140

Penny F. Ford-Carleton: so there's not really an overall page, one per say, it's just that collectively. These sections are about 4 pages.

90

00:13:25.870 --> 00:13:41.810

Penny F. Ford-Carleton: After the review there is a second phase of evaluation and a subset of the applicants to submit. The pre proposals are selected to submit full proposals, and again to the same online application system.

91

00:13:41.990 --> 00:13:53.740

Penny F. Ford-Carleton: And this form is approval to about 10 pages again with word limits for all the different sections. then the final phase that is unique to this program

92

00:13:53.760 --> 00:14:03.460

Penny F. Ford-Carleton: is called a deep dive. So a subset of applications from the full proposals are selected to participate in this deep dive evaluation.

93

00:14:04.190 --> 00:14:10.490

Penny F. Ford-Carleton: this deep dive, the the posers or the teams, are assigned

94

00:14:10.530 --> 00:14:22.490

Penny F. Ford-Carleton: executive mentors and a project facilitator that over 2 week period can delve into some of the issues that might be challenging to

95

00:14:22.490 --> 00:14:31.220

Penny F. Ford-Carleton: proposal forward. So this is has been proven to be of extreme value to teams. So even if a team does not move

96

00:14:31.360 --> 00:14:38.440

Penny F. Ford-Carleton: towards an award, the there's this benefit of having had the deep dive consultation.

97

00:14:39.230 --> 00:14:41.400

Penny F. Ford-Carleton: So on the next slide.

98

00:14:42.100 --> 00:14:44.910

Penny F. Ford-Carleton: and any of my colleagues can

99

00:14:45.510 --> 00:14:53.900

Penny F. Ford-Carleton: add color at any point. I don't know, Steve, if you wanted to add any color about the the deep dive process. It's so unique to

100

00:14:55.630 --> 00:15:01.370

Penny F. Ford-Carleton: to this system and based on a successful yeah, I'd be happy to

101

00:15:02.850 --> 00:15:06.880

Steve Schachter: the the deep dive. Evaluation is key

102

00:15:07.150 --> 00:15:13.210

Steve Schachter: for our program, because it validates that a proposal is

103

00:15:13.330 --> 00:15:16.820

Steve Schachter: at the right stage, has the right team.

104

00:15:17.120 --> 00:15:22.880

Steve Schachter: addresses the right problem. and it's poised for success. Assuming

105

00:15:24.390 --> 00:15:37.530

Steve Schachter: the availability of resources through our program. the folks that conduct the deep dive become the mentors for the project team in the event that that project is funded.

106

00:15:37.750 --> 00:15:39.360

Steve Schachter: and so that relationship

107

00:15:39.540 --> 00:15:42.600

Steve Schachter: can last up to several years.

108

00:15:42.900 --> 00:15:46.490

Steve Schachter: depending how long a project is being supported by

109

00:15:46.510 --> 00:15:47.460

Steve Schachter: the hubs.

110

00:15:48.830 --> 00:15:53.520

Steve Schachter: So the the deep dive team has extensive experience

111

00:15:53.690 --> 00:16:00.210

Steve Schachter: and many phases of commercializing medical technology. and

112

00:16:00.660 --> 00:16:03.140

Steve Schachter: it will be up immense

113

00:16:03.310 --> 00:16:12.920

Steve Schachter: help to project teams in this program, which means you Don't, have to have been a serial entrepreneur or a serial inventor serial

114

00:16:13.110 --> 00:16:16.950

Steve Schachter: commercializer, in order to be successful in this program.

115

00:16:17.580 --> 00:16:22.360

Penny F. Ford-Carleton: Great, Thank you. And I see there is a question about our mission sit.

116

00:16:22.650 --> 00:16:34.290

Penny F. Ford-Carleton: and how best to ensure that. So once again, there's a great deal of information on the Institute's website. so that can be very helpful, knowing if there is an alignment.

117

00:16:35.450 --> 00:16:53.160

Chuck Montague: I don't know, Michael, I know, is not on the call any group, and I know we have this. They're talking about a mission fit here and and from mission fit. I'm going to post the link to the Institutes and the contacts there and their emails, and and you should reach out to the.

118

00:16:53.190 --> 00:16:59.740

Chuck Montague: to the Ics to find out about mission fit again. All other questions should come to the hubs.

119

00:16:59.980 --> 00:17:13.390

Chuck Montague: but i'll post that link, and for the mission fit if it me there. The question was, how can we make sure that we're aligned with the focus lines of the research centers, and that's how you talk to them.

120

00:17:13.500 --> 00:17:17.349

Chuck Montague: So your first time your first line is going to their website.

121

00:17:17.369 --> 00:17:25.790

Penny F. Ford-Carleton: and if that doesn't answer your questions. Then you can go to program officers. So you've got that that escalation half

122

00:17:26.170 --> 00:17:32.250

Penny F. Ford-Carleton: so general application information. Sometimes folks don't

123

00:17:32.290 --> 00:17:49.720

Penny F. Ford-Carleton: refer to the frequently asked questions, because it might not be clear that many of the questions that come up really are addressed in that particular document so become familiar, not only with the solicitation, but also with the free, frequently ask questions.

124

00:17:50.240 --> 00:17:57.570

Penny F. Ford-Carleton: Now there are 3 caveats here. One is, if your project addresses a mental health disorder.

125

00:17:57.740 --> 00:18:05.540

Penny F. Ford-Carleton: You're encouraged to provide preliminary data that uses quantitative objective measures for outcomes.

126

00:18:05.820 --> 00:18:14.250

Penny F. Ford-Carleton: not just subjective survey, information. or behavioral information.

127

00:18:14.520 --> 00:18:19.280

Penny F. Ford-Carleton: and then incorporate these procedures. These measures into your proposal.

128

00:18:20.300 --> 00:18:28.270

Penny F. Ford-Carleton: so only second only Ir be exempt or minimal risk. Clinical studies can be proposed for funding

129

00:18:28.900 --> 00:18:46.650

Penny F. Ford-Carleton: and medical medical risk. Clinical studies will be conducted at a core resource that we have for all of you, and that's the George's tech Home Lab. So it's a core resource of our program, and you see more information on this particular link.

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00:18:47.050 --> 00:18:54.280

Penny F. Ford-Carleton: And then, finally, all animal models posed for funding should already be well validated.

131

00:18:54.560 --> 00:18:57.580

Penny F. Ford-Carleton: Are there any questions about these.

132

00:18:59.030 --> 00:19:03.270

Steve Schachter: There's a couple of questions in the Q. And a.

133

00:19:03.290 --> 00:19:06.510

Steve Schachter: yeah relevant to human studies

134

00:19:07.150 --> 00:19:23.890

Steve Schachter: we're referring to not funding clinical trials is that refer to no human studies or no clinical trial as per the Nih definition. So, Steve, would you want to go ahead and answer that

135

00:19:24.350 --> 00:19:32.620

Steve Schachter: a clinical study that is neither viewed by an I. Or the Institutional Review Board as exempt

136

00:19:32.920 --> 00:19:36.660

Steve Schachter: from their approval or minimal risk.

137

00:19:40.020 --> 00:19:45.780

Steve Schachter: Exempt Studies can be supported and done

138

00:19:47.110 --> 00:19:50.690

Steve Schachter: anywhere at at the discretion of the propos here.

139

00:19:52.140 --> 00:20:00.310

Steve Schachter: Minimal risk studies need to be conducted at the home lab facility, and we have the

140

00:20:02.420 --> 00:20:04.070

Steve Schachter: We have the web address here.

141

00:20:04.440 --> 00:20:08.330

Steve Schachter: If you if you want the program to pay for it.

142

00:20:09.900 --> 00:20:13.540

Steve Schachter: Proposers are are free to have other clinical work

143

00:20:13.640 --> 00:20:26.110

Steve Schachter: done during the performance period of of their stay in the in the hubs. But those clinical studies would not be paid for out of the budget for this program.

144

00:20:28.640 --> 00:20:32.690

Penny F. Ford-Carleton: Great thanks, Steve. So I hope I hope that

145

00:20:32.800 --> 00:20:36.140

Penny F. Ford-Carleton: clear that out. So on the next slide.

146

00:20:37.610 --> 00:20:51.040

Penny F. Ford-Carleton: So these are the application sections that have board limits so clinical needs, standard of care. You must identify a target indication, and it's standard of care.

147

00:20:51.310 --> 00:20:55.930

Penny F. Ford-Carleton: And what are the limitations of the current modalities of treatment

148

00:20:56.590 --> 00:20:58.240

Penny F. Ford-Carleton: and diagnostics?

149

00:20:59.010 --> 00:21:06.400

Penny F. Ford-Carleton: Second, what is your community impact relative to disease, ethnicity, geographic care, delivery system.

150

00:21:07.270 --> 00:21:17.570

Penny F. Ford-Carleton: solution, description, and how it advances upon current neuro technology and patient here. And why is it novel innovative, transformative

151

00:21:18.050 --> 00:21:26.990

Penny F. Ford-Carleton: mission fit. We've spoken about relative to being aligned with the participating organizations. Next slide

152

00:21:30.900 --> 00:21:43.960

Penny F. Ford-Carleton: you may upload, supporting information, one page in Pdf. Format the short paper overview image. Other documents that describe work to date and provides data

153

00:21:45.000 --> 00:21:54.750

Penny F. Ford-Carleton: solicitations did again, how your solution is responsive to the solicitation. Analyze with Nih on priorities

154

00:21:55.290 --> 00:22:05.280

Penny F. Ford-Carleton: and the post scope of work with the deliverables, milestones, timeframes to advance the product to a first in human prototype.

155

00:22:06.130 --> 00:22:09.400

Penny F. Ford-Carleton: then the team, the environment

156

00:22:09.710 --> 00:22:19.900

Penny F. Ford-Carleton: over, you have team members, backgrounds, what resources are available and collectively, why do they have the experience and resources to be successful

157

00:22:20.350 --> 00:22:29.220

Penny F. Ford-Carleton: in this section? Please include? There's another section relative to plans for diversity, inclusion, and equity in your team.

158

00:22:29.670 --> 00:22:35.040

Penny F. Ford-Carleton: One element that's Terry terribly important in terms of the composition of

159

00:22:36.170 --> 00:22:38.200

Penny F. Ford-Carleton: this team

160

00:22:38.610 --> 00:22:41.720

Penny F. Ford-Carleton: is there is a clinical collaborator.

161

00:22:42.570 --> 00:22:44.230

Penny F. Ford-Carleton: Next slide, please.

162

00:22:46.700 --> 00:22:52.720

Penny F. Ford-Carleton: and leadership and team composition. I mentioned workforce, diversity.

163

00:22:53.330 --> 00:22:55.180

Penny F. Ford-Carleton: regulatory path.

164

00:22:55.520 --> 00:23:01.600

Penny F. Ford-Carleton: and then we expect and hope that teams will require

165

00:23:01.620 --> 00:23:03.250

Penny F. Ford-Carleton: additional assistant

166

00:23:03.280 --> 00:23:09.560

Penny F. Ford-Carleton: from the blueprint hubs, and so there are check boxes to indicate what support might be required.

167

00:23:10.630 --> 00:23:12.310

Penny F. Ford-Carleton: So on the next slide

168

00:23:14.260 --> 00:23:24.730

Penny F. Ford-Carleton: we've learned lessons from the fall cycle of submissions. And there are some common reasons for rejection that that Steve will describe.

169

00:23:24.880 --> 00:23:39.060

Penny F. Ford-Carleton: Penny sounds like you. You need some. They're they're doing construction in my home home. I'm: Sorry, everyone. So we got dust everywhere. Yeah. Why, don't you get a glass of water? I I I'll take it from here.

170

00:23:39.140 --> 00:23:40.860

Steve Schachter: Okay. So

171

00:23:41.410 --> 00:23:50.760

Steve Schachter: first of about the stage of maturity. This is a key consideration for the program. You remember that innovation cycle that we showed earlier.

172

00:23:51.710 --> 00:23:57.670

Steve Schachter: which goes from Id all the way through standard of care. This program is at

173

00:23:57.740 --> 00:23:59.940

Steve Schachter: a relatively early stage.

174

00:24:00.400 --> 00:24:03.730

Steve Schachter: where there has been proof of concept

175

00:24:04.030 --> 00:24:14.950

Steve Schachter: and the main mission or the main objective of entering in the program is to de-risk the technology and to work towards

176

00:24:15.120 --> 00:24:19.230

Steve Schachter: a prototype that could then be used for

177

00:24:20.430 --> 00:24:23.680

Steve Schachter: definitive clinical studies, either safety or effort to see

178

00:24:25.170 --> 00:24:27.570

Steve Schachter: under FDA

179

00:24:30.110 --> 00:24:37.160

Steve Schachter: observation of, you know, monitoring. So sometimes we get proposals that are too early

180

00:24:37.430 --> 00:24:42.290

Steve Schachter: it. There's no animal data yet. There's you know. It's just an idea that's too early.

181

00:24:42.510 --> 00:24:54.770

Steve Schachter: On the other hand, sometimes we get projects that where they were the teams already met with the FDA. They have a regulatory pathway there about, you know they're They're on the cusp of

182

00:24:55.360 --> 00:25:02.830

Steve Schachter: they. They've made 10 or 20 prototypes. They're ready to start clinical studies that's to advance for our program. And

183

00:25:03.060 --> 00:25:13.960

Steve Schachter: as Penny mentioned, the the Nih. Has companion programs to ours, called you G 3, and you H. 3

184

00:25:16.730 --> 00:25:20.100

Steve Schachter: to and you 44 to

185

00:25:20.450 --> 00:25:22.930

Steve Schachter: accommodate projects at that stage.

186

00:25:23.930 --> 00:25:30.800

Steve Schachter: So yeah. if you're not a 100% sure of where you are on that innovation cycle.

187

00:25:32.410 --> 00:25:39.100

Steve Schachter: you can try to email us and see if we can help answer that question. But that's

188

00:25:39.280 --> 00:25:45.340

Steve Schachter: the leading reason for rejection from our first cycle, Penny, you ready to go.

189

00:25:49.460 --> 00:26:04.290

Penny F. Ford-Carleton: So stage with maturity. You just discuss, then. Team composition is the second, and we find that some teams just lack critical areas. Next piece, particularly as I mentioned, the clinical collaboration

190

00:26:05.420 --> 00:26:07.160

Penny F. Ford-Carleton: impact is the third.

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00:26:07.680 --> 00:26:14.320

Penny F. Ford-Carleton: Some people are just, not significant, not significantly different from existing products.

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00:26:14.500 --> 00:26:23.420

Penny F. Ford-Carleton: So it's important to do that competitive analysis. I'm Sure, as you all know. second area of impact is, there might be only marginal impact.

193

00:26:23.770 --> 00:26:32.650

Penny F. Ford-Carleton: not a clinical problem. And we're looking at it groundbreaking, significant, not incremental impact and mission fit.

194

00:26:33.200 --> 00:26:34.840

Penny F. Ford-Carleton: We've talked about that.

195

00:26:34.910 --> 00:26:40.280

Steve Schachter: Yeah. And while we're on this slide I want to emphasize the team composition point.

196

00:26:41.100 --> 00:26:44.360

Steve Schachter: Our expectation is that there will be

197

00:26:44.710 --> 00:26:49.380

Steve Schachter: a clinician on the team that has

198

00:26:50.010 --> 00:26:55.350

Steve Schachter: insight into the unmet medical need that is being addressed by the proposal

199

00:26:55.960 --> 00:26:59.280

Steve Schachter: properly. Preferably somebody who has

200

00:26:59.340 --> 00:27:02.550

Steve Schachter: extensive insight into that, because it's

201

00:27:02.620 --> 00:27:05.320

Steve Schachter: represents a patient population that they

202

00:27:05.620 --> 00:27:09.760

Steve Schachter: no well, either through clinical care or research. But

203

00:27:10.750 --> 00:27:14.510

Steve Schachter: that's a key for us. It's the input of the clinician

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00:27:14.610 --> 00:27:20.720

Steve Schachter: to define the unmet medical need to say what's lacking

205

00:27:21.120 --> 00:27:22.490

Steve Schachter: in available

206

00:27:22.910 --> 00:27:25.960

Steve Schachter: other options that are available now.

207

00:27:26.320 --> 00:27:38.570

Steve Schachter: and to make a compelling case that this proposed project We'll have significant impact. Be transformational on the clinical condition.

208

00:27:38.840 --> 00:27:40.790

Steve Schachter: Thanks, Kenny. You can take.

209

00:27:41.080 --> 00:27:54.470

Penny F. Ford-Carleton: There are a couple of questions. Here one was a question You might already have seen this. Can we propose a device plus an FDA approved molecule, or is this therapeutic only

210

00:27:58.940 --> 00:28:01.030

Penny F. Ford-Carleton: Steve, Would you like to respond to that

211

00:28:02.180 --> 00:28:03.200

Penny F. Ford-Carleton: or Chuck?

212

00:28:09.410 --> 00:28:23.880

Chuck Montague: We will come back to that. I can see that you're both off of audio. Okay, I'll. I was trying to try and respond to another. But yes, that is which was

213

00:28:24.040 --> 00:28:26.350

Chuck Montague: what's the question there

214

00:28:26.620 --> 00:28:36.020

Chuck Montague: was on the on the FDA approved drug. Yeah, if it's a. If it's an approved drug, it's already approved, and you have a device for delivery.

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00:28:36.050 --> 00:28:39.860

Chuck Montague: and the devices is what is is under development

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00:28:40.100 --> 00:28:43.340

Chuck Montague: that is, within the scope of our project.

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00:28:45.400 --> 00:28:58.380

Penny F. Ford-Carleton: Great. Could you expand on that chuck or Steve question here? Applications will not be considered for products not regulated by the FDA. Could you please explain this more completely, since most

218

00:28:58.480 --> 00:29:02.420

Penny F. Ford-Carleton: of new ideas are not required by the FDA.

219

00:29:03.140 --> 00:29:11.350

Steve Schachter: If your product can come to the market legitimately without the approval of the FDA as a commodity

220

00:29:12.830 --> 00:29:18.830

Steve Schachter: something a person could pick up at in the store. The you know, Drugstore, whatever

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00:29:18.980 --> 00:29:26.430

Steve Schachter: doesn't require. FDA approval at all. Look at like many apps, for example, for the smartphones

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00:29:26.720 --> 00:29:30.600

Steve Schachter: that is not within scope of this program.

223

00:29:32.330 --> 00:29:38.400

Penny F. Ford-Carleton: Great. Thank you. There's a question. Will this be this recording be available. And yes, it will be

224

00:29:39.920 --> 00:29:42.370

Penny F. Ford-Carleton: okay, Jessica, next slide, please.

225

00:29:44.160 --> 00:29:55.360

Penny F. Ford-Carleton: So time one. I'm: sure. You all know. Next week, March sixteenth is the day for free proposal. Submission you would be notified by April eleventh.

226

00:29:55.710 --> 00:30:06.250

Penny F. Ford-Carleton: for proposals invited. Full proposals are then invited. May Ninth and the Atlantic or Deadline is May, 9

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00:30:06.430 --> 00:30:09.860

Penny F. Ford-Carleton: and applicants are then notified. June 20, seventh.

228

00:30:10.850 --> 00:30:17.090

Penny F. Ford-Carleton: if invited for a deep dive. That will be between July, Fourth and nineteenth.

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00:30:17.090 --> 00:30:37.460

Penny F. Ford-Carleton: and, as we mentioned, there's significant interaction which is proven to be a great value between the teams and the executive mentors. So this is the timeline for our spring summer application. We will be doing 2 solicitations a year, so the second solicitation will be announced in the fall

230

00:30:38.930 --> 00:30:40.610

Penny F. Ford-Carleton: next slide, please.

231

00:30:41.380 --> 00:30:47.310

Steve Schachter: Now we have a companion seedling program again. This is by invitation only.

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00:30:47.430 --> 00:30:58.960

Penny F. Ford-Carleton: These are proposals that have gone through to through the pre proposal or full post, electric, full proposal, stage or deep dive, and they would then be redirected.

233

00:30:59.360 --> 00:31:08.040

Penny F. Ford-Carleton: but invited to participate in the seedling program. And this is a new budget of up to $50,000. The one would need to resubmit

234

00:31:08.070 --> 00:31:15.810

Penny F. Ford-Carleton: with milestones on how gaps identified during the review process would be addressed over a 6 month period.

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00:31:16.110 --> 00:31:21.600

Penny F. Ford-Carleton: So this is a kid to a planning grant. Then the 2 hubs provide training and mentoring

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00:31:21.830 --> 00:31:28.190

Penny F. Ford-Carleton: to help strengthen a proposal for subsequent applications. Next slide, please.

237

00:31:30.810 --> 00:31:40.480

Penny F. Ford-Carleton: So final additional information. The earliest anticipated start date for selected for proposals is November 2023.

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00:31:40.660 --> 00:31:49.480

Penny F. Ford-Carleton: The AIM of the hub inc later projects once again, just to reinforce it should be to develop prototype first, and human studies

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00:31:49.740 --> 00:32:03.390

Penny F. Ford-Carleton: and projects that are already ready for clinical studies to consider the ut 3 you h 3 blueprint that tech translator or you 44, a small business translator, and these deadlines will come up in the fall.

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00:32:04.040 --> 00:32:09.920

Penny F. Ford-Carleton: Now the initial anticipated performance period for our program is 12 months

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00:32:10.060 --> 00:32:18.730

Penny F. Ford-Carleton: that can be renewed for an additional 3, 12 month period, with approval from the leadership of the Hubs and Nih.

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00:32:19.270 --> 00:32:29.140

Penny F. Ford-Carleton: just to reiterate awards, rarely succeed 500,000 per year and indirect costs will be provided. The institutions federally negotiated rate

243

00:32:29.820 --> 00:32:36.240

Penny F. Ford-Carleton: the earliest start date for the seedlings, as well as the pro awards is november 23.

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00:32:36.900 --> 00:32:38.660

Penny F. Ford-Carleton: So next slide, please.

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00:32:40.790 --> 00:32:45.560

Penny F. Ford-Carleton: So these are resources that we will are able to make

246

00:32:45.580 --> 00:33:02.070

Penny F. Ford-Carleton: available to you. Someone asked about the slides and the recording. You can see it's www.simit.org slash center for innovative hy, for neuro, tech, hype and advancement slash. Events

247

00:33:02.640 --> 00:33:09.270

Penny F. Ford-Carleton: frequently asked questions. As I mentioned, earlier. It's important to be come to become familiar with those questions.

248

00:33:09.610 --> 00:33:16.510

Penny F. Ford-Carleton: We have been scheduling office hours over the last month. This is the Debbie's email.

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00:33:16.520 --> 00:33:34.680

Penny F. Ford-Carleton: They have filled up very rapidly. So actually through tomorrow we are build up. So if one would like to request an office hour, I think the best we could do at this point is, respond to questions in in your

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00:33:34.680 --> 00:33:36.790

Penny F. Ford-Carleton: If you you just email us.

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00:33:36.880 --> 00:33:47.040

Penny F. Ford-Carleton: these office hours Will designed to be like just 15 min section session. So we've been able to schedule a number of them.

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00:33:47.380 --> 00:33:55.330

Penny F. Ford-Carleton: We have a general information here info at blueprint, and then this this phone number.

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00:33:55.790 --> 00:34:00.110

Penny F. Ford-Carleton: So we hope that these resources will be of value.

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00:34:00.130 --> 00:34:01.060

Penny F. Ford-Carleton: and

255

00:34:01.390 --> 00:34:10.550

Penny F. Ford-Carleton: maybe if we could just go to the next good luck slide that's that's all we have for the formal presentation. But why, Don't? We? We've got it

256

00:34:10.650 --> 00:34:15.639

Penny F. Ford-Carleton: time for additional questions, and we really welcome

257

00:34:15.710 --> 00:34:21.590

Penny F. Ford-Carleton: those questions, so I don't see open questions at this moment.

258

00:34:21.900 --> 00:34:23.739

Penny F. Ford-Carleton: So whoever

259

00:34:24.580 --> 00:34:28.370

Penny F. Ford-Carleton: post the question will be the next one in the queue.

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00:34:30.620 --> 00:34:34.570

Chuck Montague: Well, Steve, I I think the question you have, if you that you answered

261

00:34:34.600 --> 00:34:40.429

Chuck Montague: there with the question. Do you want to expand on that about the prototype Not being ready? Just

262

00:34:41.770 --> 00:34:44.679

Steve Schachter: well? The

263

00:34:46.530 --> 00:34:50.520

Steve Schachter: questioner said that they're ready for a clinical trial.

264

00:34:51.679 --> 00:35:02.260

Steve Schachter: but they so just that statement alone would make us think that it's probably too far advanced for our program. But then the follow up statement said

265

00:35:02.460 --> 00:35:10.500

Steve Schachter: that they need to build a prototype. So the the prototype was adding a bunch of other sensors in it.

266

00:35:10.910 --> 00:35:15.250

Chuck Montague: but then it also said it was based on a predicate device there.

267

00:35:15.690 --> 00:35:16.360

Steve Schachter: Oh.

268

00:35:16.540 --> 00:35:20.420

Chuck Montague: and if it's a if it's based on a predicate of 5, 10, K.

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00:35:20.610 --> 00:35:33.420

Chuck Montague: With a predicate device, this program is particularly targeted to Pm. As. or de novos, or 5 10 K. That will require a a clinical trial on them.

270

00:35:33.550 --> 00:35:42.670

Chuck Montague: But if you're just, if you're just adding it. And you think you can get through with the 5, 10 K. With a predicate device. It's probably not not

271

00:35:42.780 --> 00:35:45.420

Chuck Montague: appropriate for this program.

272

00:35:47.040 --> 00:35:49.570

Penny F. Ford-Carleton: Jessica. I'm wondering if you could go back

273

00:35:49.590 --> 00:35:56.160

Penny F. Ford-Carleton: for slides. I believe it's 4 slides to the lessons that we've learned

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00:35:56.340 --> 00:36:00.270

Penny F. Ford-Carleton: from this first cycle. Thank you up submission

275

00:36:00.450 --> 00:36:02.310

Chuck Montague: because these one more.

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00:36:02.510 --> 00:36:09.330

Penny F. Ford-Carleton: one more. Thank you, because these are the common pitfalls, and even though

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00:36:09.850 --> 00:36:15.520

Penny F. Ford-Carleton: folks hear us discuss them sometimes, it's not completely clear.

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00:36:15.740 --> 00:36:22.470

Penny F. Ford-Carleton: so do we have any other questions relative to these 4

279

00:36:23.970 --> 00:36:25.830

common reasons.

280

00:36:25.900 --> 00:36:43.880

Penny F. Ford-Carleton: or anything else for those of you that have submitted a proposal. And now, considering resubmission, if you have a question specific to your proposal. We won't read it to the group. We'll just respond to it. However, if there are generic questions, you've been through the cycle.

281

00:36:43.880 --> 00:36:51.170

Penny F. Ford-Carleton: so you might have something to ask that would be a value to others. So I see a question just came in

282

00:36:54.360 --> 00:37:06.960

Penny F. Ford-Carleton: P. Debbie. Would you like to respond to this? The resources that are listed on the potential resources? Would these be budgeted in the award, or they additional resources available?

283

00:37:07.070 --> 00:37:23.440

Debbie Lee (she/her): Sure, i'm happy to take that. So the potential resources that are listed on the page are actually, in addition to the amount that we will award to you. So you don't have to budget for them in the allotted. The restricted amounts that we have available for you.

284

00:37:24.660 --> 00:37:26.050

Penny F. Ford-Carleton: Great. Thank you.

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00:37:26.140 --> 00:37:38.120

Penny F. Ford-Carleton: Another question. Can we consider, or can we include our preliminary data from prior human subject testing and the pre proposal for proof of concept?

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00:37:38.460 --> 00:37:41.390

Steve Schachter: Yeah, yes, the answer is yes. And

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00:37:42.480 --> 00:37:44.430

Steve Schachter: the proof of concept

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00:37:44.940 --> 00:37:56.720

Steve Schachter: can't be based on human data, particularly true for some conditions or situations where there is not a validated animal model. For example, some

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00:37:58.120 --> 00:38:04.680

Steve Schachter: I see your mental health. This orders of interest it to this program. So yes.

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00:38:04.850 --> 00:38:08.700

Steve Schachter: if you have for the preliminary data from

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00:38:09.000 --> 00:38:12.910

Steve Schachter: one or more human subjects, please include it.

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00:38:14.160 --> 00:38:28.310

Penny F. Ford-Carleton: Okay, and thank you. Someone just typed a question that we will not answer online that specifically to their proposal. Steve will send a confidential type, a confidential answer

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00:38:28.770 --> 00:38:43.420

Penny F. Ford-Carleton: to you, so I just encourage others. If you have questions detailed, questions that you want answered, and of course not shared with the group overall. Just feel free to

294

00:38:44.090 --> 00:38:46.750

Penny F. Ford-Carleton: type them. Or again, you can type them.

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00:38:48.140 --> 00:38:51.630

Penny F. Ford-Carleton: You can send them to to Debbie Lee.

296

00:38:56.320 --> 00:39:04.850

Steve Schachter: Okay, so I think that was answered.

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00:39:05.060 --> 00:39:16.030

Steve Schachter: And information, other types of webinars on top of of interest to the neuro technology community. So I mean, please stay tuned for advanced notices

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00:39:16.080 --> 00:39:18.000

Steve Schachter: of those Webinars

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00:39:19.400 --> 00:39:22.280

Steve Schachter: as well. And as Penny said, we're going to have to

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00:39:22.390 --> 00:39:25.350

Steve Schachter: solicitations a year. The next one would be this fall.

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00:39:25.720 --> 00:39:28.150

Steve Schachter: and

302

00:39:28.870 --> 00:39:35.020

Steve Schachter: if you debating whether to wait or not.

303

00:39:36.130 --> 00:39:38.380

Steve Schachter: You know you have that option.

304

00:39:39.270 --> 00:39:39.900

Steve Schachter: Okay.

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00:39:41.330 --> 00:39:48.400

Chuck Montague: actually, our our cycle 3 is scheduled for July end of July.

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00:39:48.650 --> 00:39:49.420

Penny F. Ford-Carleton: Great.

307

00:39:50.480 --> 00:39:52.000

Penny F. Ford-Carleton: and I see that

308

00:39:52.180 --> 00:39:58.410

Penny F. Ford-Carleton: Michael Wilson, a key champion on the Nih leadership team

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00:39:58.460 --> 00:40:00.100

Penny F. Ford-Carleton: to

310

00:40:00.220 --> 00:40:19.940

Penny F. Ford-Carleton: responsible and supporting this program, Michael just joined us. Mike. I know, Michael, I know you haven't had the benefit of the whole series. But you've heard this, Webinar before. That's separate conversation about. There are other. So would you like to just

311

00:40:19.940 --> 00:40:22.520

Penny F. Ford-Carleton: say anything to this particular group.

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00:40:23.030 --> 00:40:26.570

Michael Wolfson: Yeah, I I just want to encourage you to, you know.

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00:40:26.980 --> 00:40:34.550

Michael Wolfson: do 2 things. One is, if you have any questions ask during this Webinar during office hours

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00:40:34.620 --> 00:40:46.430

Michael Wolfson: or to the blueprint tech inbox. They're very responsive. and the other one is, Make sure that what you're proposing to do fits within the mission of an Nih computer center.

315

00:40:46.490 --> 00:40:49.240

Michael Wolfson: So the solicitation is run by

316

00:40:49.360 --> 00:40:58.300

Michael Wolfson: Mgb. And no Tech harbor out of Hopkins Sinta. So those organizations are running this. Listen: They're evaluating their funding stuff.

317

00:40:58.750 --> 00:41:15.490

Michael Wolfson: But the money comes from Nih, and Nih is not going to provide money for things that do not fit their mission, and only a subset of Nih is participating in this program. So please check with the Nih points of contacts to make sure that your project is within mission.

318

00:41:15.740 --> 00:41:25.680

Michael Wolfson: and I staff will not comment on merit or interest, or answer questions about the solution. Only about is it something that they could fund?

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00:41:26.820 --> 00:41:32.290

Michael Wolfson: Every other question should go to the fine folks you see here.

320

00:41:34.320 --> 00:41:45.150

Penny F. Ford-Carleton: Great thanks, Michael Rubin. Anyone else from Nih. Would you like to to comment, or anyone from either hub any more questions again. We still have time.

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00:41:45.600 --> 00:41:47.830

Penny F. Ford-Carleton: But thank you, really appreciate

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00:41:48.220 --> 00:41:52.250

Penny F. Ford-Carleton: your being here and your questions.

323

00:41:53.030 --> 00:41:55.880

Penny F. Ford-Carleton: So if there isn't anything else.

324

00:41:56.410 --> 00:41:57.840

Steve Schachter: I think that

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00:41:58.330 --> 00:42:02.720

Penny F. Ford-Carleton: that we're all set to sign up. So again. Thank you.

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00:42:04.810 --> 00:42:06.450

Penny F. Ford-Carleton: Will sign off.

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00:42:11.470 --> 00:42:12.900

Penny F. Ford-Carleton: Thanks, Jessica.

328

00:42:14.410 --> 00:42:18.820

Chuck Montague: What's is this recorded? I oh, it it's recording. I see that thing now, yeah.

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00:42:19.620 --> 00:42:25.580

Penny F. Ford-Carleton: is it? Is the recording available with the slides.

330

00:42:25.760 --> 00:42:26.160

Penny F. Ford-Carleton: I.