NATIONAL INSTITUTES OF HEALTH
Moderator: Gina Ord
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3:00 pm CT

Operator: Please stand by. We are about to begin. Good day and welcome to the National Institutes of Health ATN for FOA Publication Conference Call. As a reminder today's conference is being recorded. At this time, I'd like to turn the conference over to Dr. Bill Kapogiannis. Please go ahead.

Bill Kapogiannis: Thank you. Good afternoon everyone, and thank you for your interest and participation on today's conference call regarding the FOAs HD16035 and 16040 for the Adolescent Medicine Trials Network for HIV and AIDS Interventions research program grants and coordinating center. I am Bill Kapogiannis; I'm the program director.

I work out of the Maternal and Pediatric Infectious Disease branch at NICHD. A brief background, I think most all of you on the call probably participated in the prior Webinar that was conducted on the thirteenth of October this year, which provided selected highlights of the funding opportunity announcements and discussed a few of the selected FAQs, and this Webinar has been posted online at www.nichd.nih.gov.

So, little housekeeping items for this call. I will aim not to repeat what was in the Webinar, so please do visit the NICHD Web site that I've just described if you would like to see what was covered. I will take a few more FAQs that I will discuss here; some selected FAQs next, and then open it up at that point for Q&A and open discussion.

This conference call will be transcribed and posted alongside the Webinar on the NICHD Web site very soon. All FAQs will also be compiled and uploaded to the NICHD Web site as well.

Please know that if I do not or cannot get to your question during this call, please email me directly at the address on the notice for the Webinar and call.

So with that, I'm going to go ahead and begin with the first selection of FAQs. So what are non-responsive topics? And those are formative, biomedical, behavioral, or community-level interventions lacking a clear developmental trajectory linked to large-scale efficacy or effectiveness evaluations.

Studies evaluating or comparing anti-retroviral treatment strategy trials, stand-alone pharmacokinetic, pharmacodynamic evaluations of anti-retroviral therapy and research focused only on neuro cognitive dysfunction and HIV.

Next FAQ would be what are the required components of the U-19 application? There are four here.

There's the overall component, the management core, analytic core, and the research projects that are three to four, so a minimum of three, maximum of four projects.

The next FAQ is what are optional components of the U-19 application? And those are, there are two of them, the scientific core or cores, and then the pilot project or projects. Again, there's a minimum of one, or a maximum of two.

Next FAQ: Must I ensure community relationship establishment and engagement? The answer is yes. This is a requirement in your application and should be done before any work is planned, and should be an integral part of ongoing network research activities.

The next FAQ is does a community advisory board (CAB) alone fulfill the requirement continuity engagement? The answer is no. The youth CAB must be constituted at the local level and is an additional requirement in your application. Local youth CABS must be engaged again at the beginning, before work is planned and again should be an integral part of ongoing research activities.

Next one is does or do the optional pilot projects; project or projects need to link up to a larger scale trial?

The answer is yes.This FOA will also support formative, test of concepts/pilot clinical studies (or pilot projects) in HIV infected and at risk youth populations if they are directly linked with larger-scale efficacy intervention for evaluation among these populations and proposed in the same application.

Next is if the inclusion of perinatal HIV infected adolescents allowed? The answer is yes, as long as the proposed work fits within the objectives and the scope of the FOA, this is allowable.

The next FAQ is what does, and this is about the U-24, what does the 250,000 dollars in direct cost for the ATN coordinating center cover?

The ATN coordinating Center scope of work includes operational support, regulatory infrastructure, data management, and innovative analytic methodology, tracking and reporting of study progress and so on to support cross network and emerging high-priority study protocols only, not the U-19 research projects that are included in the applicationsto this FOA.

So moving onto an FAQ on application review. How will the review of the U-19 and U-24 applications be conducted? A special emphasis panel or a SEP with relevant content expertise will be convened by the NICHD/NIH.

Next one, again about review, after an NIH peer review and a National Advisory Child Health and Human Development Council reviews the U-19 applications, what will NIH funding decisions consider?

There are five elements here. Scientific and technical merit of the proposed project as determined by scientific peer review, availability of funds, the relevance of the proposed project for the program priorities, compliance with data and resource-sharing policies as appropriate, and finally NIH discretion with application selection to ensure that a synergistic range of topics are addressed.

In other words, prevention approaches and specific parts of the continuum for example, diverse populations, and geographic distribution, in order to form a multi-focus collaborative project.

Moving on to some general FAQs, will ATN IV participate in protocols supported by other networks or individual grants? Yes. ATN has a history of participating in protocols initiated by other networks and funded by individual awards.ATN also has a history of participating with other federal agencies such as CDC and HRSA.

Next question, will ATN IV continue to support protocols developed or initiated during the previous cycle? The answer to this is subject to the deliberations of and prioritization by the ATN executive committee.

Next is how will a network of independent U-19s operate efficiently and communicate with each other to achieve desired results in a timely fashion?

Although each U-19 will have its own research projects addressing ATN relevant research and clinical questions, each U-19 PI and U-24 PI, as well as the research project PI and core PIs will meet on a regular basis to discuss both scientific and logistic matters important to the ATN. In addition, the network will be guided by an executive committee composed of NIH collaborators, community membership, U-19 PI and U-24 PIs. And there will be a start-up meeting after the successful applicants are funded.

Next question, will sites and their investigators be able to contribute and shape the science of the ATN? Yes. All applicants are encouraged to forge close partnership with candidate sites as they consider in participating in each U-19.Those relationships that meaningfully and substantially contribute, for example, protocolconceptualization, development, leadership, analysis and datadissemination from publications and so on, to the scientific agenda of ATN are also encouraged. That will conclude the few selected questions, FAQs that I wanted to go over.

Operator? I think we are ready to move to the open session for discussion and Q&A.

Operator: Yes. Thank you. If you'd like to ask a question please signal by pressing star one on your telephone keypad. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment.

A voice prompt on your phone line will indicate when your line has been opened. Again, press star one to ask a question; I'll pause for just a moment to allow everyone an opportunity to signal for a question. Again as a reminder that is star one if you have a question. And I have not questions in the queue at this time.

I do apologize. I do have questions that are in the queue now. We'll go to our first question.

Donna Futterman: Hi. This is Donna Futterman from the Bronx. Is there any provision in how you will fund this for maintaining sites? As you know, it requires quite an extensive array of experience with youth and infrastructure in order to successfully recruit and retain positive and negative use. And I didn't see any reference in the RFAs particularly to the types of sites and infrastructure that you're interested in.

Dr. Bill Kapogiannis: So, thank you for that question. This will be one of the FAQs that is published on the Web site that I referred to earlier. There is, in fact, a section in the RFA, there are actually several sections that do allude to this, and basically the FAQ will address also - what should be included in the application regarding potential sites for youth recruitment.

And, these include a plan to address youth recruitment needed for the proposed studies and estimate or project a number of youth available for recruitment, able to demonstrate in previous success with recruitment and retention of studies should also be included, performance measure and monitoring plans of all sites under the proposed program should be included, and then plans, processes, timelines, milestones and site performance monitoring need to be a part of that as well.

And, I believe that if my memory serves it's at least in the management core section of the U-19. It also may be under the research projects if I'm not mistaken.

Donna Futterman: Bill. It's very hard for me to hear you. Can you hear me right now? I can hear you. Sorry. Okay. I just didn't know if my mic was open. Do you have any suggestions for the U-19 applicants as to resources to be devoted to this site? And is there any mechanism at your end to look at sites over a couple of U-19s and trying to either make sites whole or feasible across multiple U-19s?

Dr. Bill Kapogiannis: I'm not sure I understand the question Donna. Maybe you could rephrase?

Donna Futterman: Okay. Right now the way the mechanism is structured it's all based on a very specific research plan and maybe I'm just stuck in, you know, ATN one to three, in which sites existed independently. So I was wondering if you had any advice for the U-19 applicants as to how they can make the sites whole?

And when you deliberate afterwards and try and put together a collaborative network, will there be any emphasis on that as opposed to just, you know, maybe one site will have a third of the support it needs, a different site will have four-fifths, is there any commitment down the road to try and help make the sites be functional for those who are involved in the network?

Dr. Bill Kapogiannis: So, I think I follow you a little bit better, you know, the way that the FOAs are designed, particularly the U-19, there is a much better alignment between the sites and the science right now. And I think there is every opportunity, to me it is pretty clear that this alignment exists and the sites can be a full part of the research activities network.

I think there's also the question that I already went through around whether the site investigator will even be able to contribute the science of the ATN. And I think, you know, hopefully when I covered that that also addressed that, you know, as long as there are meaningful and substantive contributions that is also an allowable and encouraged collaboration that we would like to see.

Operator: And we'll go to another question.

Bill Kapogiannis: Thank you.

Operator: Again that is star one if you wish to ask a question.

Female: For those applications that are funded, will you pick and choose amongst the projects submitted within the application or are you approving the application as a whole.

Bill Kapogiannis: The applications are reviewedin their entirety, and we will consider the review when we look at what makes sense. But, as I alluded to in one of my FAQs that I'm trying to find them, around the review criteria the, sorry. So there's one that I actually discussed and then there's one that I didn't discuss I think.

So I discussed about the considerations NICHD will make in terms of funding decisions, but also, you know, the review criteria that I didn't discuss on these FAQs and that is the standard peer review of the system apply, and additional RFA decision criteria will be used and these include on the program project as an integrated effort, specifically around coordination, cohesiveness and synergy among the research projects and cores as they relate to the common theme of the project, clear advantages of conducting the research as a program project rather than through separate research project mechanisms for both regular communication, coordination and collaboration among investigators within the program project and with the investigators within the network and the effective administrative structures for the day-to-day management of the program project.

So, you know that FAQ, plus the other one that I discussed and described in terms of looking at the scientific and technical merit, availability of funds, the relevance of the proposed project to program priorities and compliance with data and resource sharing policies, as well as the discretionary piece around NIH and looking at, you know, prevention approaches and specific parts of the continuum of care that risk populations and geographic distributions that form the collaborative network of multi-program projects. Those are all factors that will be considered as we receive the peer review results.

Operator: And again that is star one if you wish to ask a question; again star one, and we'll go to our next question.

(Bonnie): Yes. This is (Bonnie) Stanton from Wayne State University. Can you explain a bit more about how the pilot projects should be written to correspond with the main project? We just haven't been able to get much of a sense of how that would work. So do you anticipate that the pilot would be done first, and then the RO1 one would start a couple of years into the program? Or what do you mean by the relationship you're looking for?

Bill Kapogiannis: I think that it's pretty hopefully clear, and let me try to clarify if it isn't, we would like for both pilots and the linked-up, larger-scale efficacy trials to be within the same application. That does not mean however we expect them to be concurrent. I think it's reasonable to say we would like to see the proposed pilot go forward.

And then if results are promising and feasible and demonstrate that there's significant likelihood of success, then there will be go/no-go decisions that can be made with regards to the planned and proposed efficacy trial that would be in that application.

Female: So one would write the efficacy trial assuming that the pilot would be positive? But, you first do the pilot and then there'd be the go-/no-go only if the pilot were successful? Is that what you're saying?

Bill Kapogiannis: Yes. Correct. You are correct. That would be the assumption. Exactly.

Female: Thank you.

Operator: Again that is star one if you wish to ask a question. We'll now go to our next question.

(Marvin Belzer): Hi Bill. This is (Marvin Belzer), just a follow up to that last question, would we have the ability to write a, you know, R-21 and indicate kind of more generally what we would do at the next steps but say that we would be then applying to the U-24 for that two million dollar pot that's

in our phase leftover kind of these timely protocols, you know, to kind of that be more of the plan instead of actually having a full RO one already written up based on a positive R-21 like finding?

Bill Kapogiannis: So, thank you for bringing that question up (Marvin). I think that's a very good question. Again, looking at the way the initiatives are designed is as part of the U-19 application that would not be possible to do and link up to the U-24. I think you could do that separately later, but in order to propose a pilot project there would have to be a linked-up, follow-on, larger-scale efficacy trial in that U-19 application.

(Marvin Belzer): Bill? This is (Marvin). Am I still on?

Bill Kapogiannis: You are.

(Marvin Belzer): Yeah. So, just to follow up on that, would the U-19 application have to have budgeted that full RO one not knowing whether it was going to go forward or not?

Bill Kapogiannis: Yes. That is correct.

(Marvin Belzer): So what happens if the results aren't positive and then the sites are then sitting with kind of a pot of money?

Bill Kapogiannis: Yeah. I think that again facing the scenario that the results did not favor continuing into the larger-scale efficacy trial that the money would not then be there to be able to do anything else with, you know, the money would be there with the contingency that we would go into the larger-scale efficacy trial, otherwise it would get reprioritized by the network.

Operator: And again that is star one if you wish to ask a question. And we'll go to our next question.

Sylvie: Hi. This is Sylvie from Wayne State, and I'm wondering if you could comment on how you see the sections about new protocols coming down the pike being written and where it would go, because in the RFA I think it's kind of already written within the different projects but I'm not sure that's how it's set up.

Bill Kapogiannis: So, Sylvie can you please clarify for me, are you referring to the emergent across U-19 collaborative projects being discussed, or are we talking about something different?

Sylvie: No. That's it.

Bill Kapogiannis: Yeah. I'm trying to see if I can find the exact page number in the RFA that that refers to, but maybe you could just start with more generally speaking of some of the new protocols that might emerge across U-19 after funding? And, I think you wanted, you know, some of that discussed in the actual application?

Bill Kapogiannis: Yeah. So, I'm sorry your question was specifically about how much detail or what? Can you please repeat that question?

Sylvie: Yeah. It was, let's see I'm trying to think, how much detail and where in the application it would actually go?

Bill Kapogiannis: So, here's the two-part answer, the details question again you only know what you know, and if we really don't know what projects will have been funded, because we don't have a crystal ball. We can't tell. You only know what you can put down. The second part of the question is where does this plan actually best fit in your application?

It is currently, I believe, in the research strategy, the research plan, the research strategy for the research projects, and that's where it is asked for...

Sylvie: Right.

Bill Kapogiannis:...probably the best place to put it. Was there something more specific?

Sylvie: Well I guess I was just a little, yeah, I guess because you're going to have four of those, so I'm guessing then that you would just put it in the first one maybe? Yeah?

Bill Kapogiannis: Yes. So, let me see if I can clarify that, I think it can go one of two ways, and I don't think there's any particular right way. It can go either in the first of the four or three, however many you

propose. Or, it can go as something that's more broadly discussed with the overall and the PI of the U-19 and may describe which of the projects, if all of them or any of them are going to be doing this, are going to be engaged in that, so I think in either place. I don't think we need to repeat it.

Sylvie: Okay. So, just to be clear, the way it's written, it's not really written like one of the four projects would go across U-19; although, we certainly can talk about that. It's sort of written like new protocol as the science continues to evolve? So that part sounds like would go better in the overall strategy versus the individual projects?

Bill Kapogiannis: Correct. Correct.

Sylvie: Okay.

Bill Kapogiannis: Yes. That would be okay.

Sylvie: Mm-hmm. All right. Thank you.

Operator: Again star one if you wish to ask a question. We'll go to our next question now. Perhaps your line is on mute, so we're not hearing your voices at this time. Could I ask you to please pick up your handset? I'm not hearing your voice. Miss (Boyer) are you there?

Female: Sorry about that, hi I wanted to know how many U-19s will be funded?

Bill Kapogiannis: So, as I said in the FOA there is intent to fund four to five depending on priorities and all of those factors that I covered on funding availability and all of that.

Operator: Miss (Boyer) do you have any other questions?

Female: No. Thank you. That was it. Thank you.

Operator: Thank you. And we have no other questions in the queue at this time. Once again that is star one if you wish to ask a question. We'll go to our next question.

Bonita Stanton: Yes. This is Bonita Stanton again from Wayne State. Could you comment a bit on how you envision the analytic core to work? Are you anticipating that the statisticians who are involved in writing the individual RO one's would then migrate out of the RO one and be exclusively in the analytic core? Or, have you given much thought to how we would navigate from a traditional RO one where the statistician is directly related to that RO one? And, yet at the same time trying to have a core that benefits all of the individual sites?

Bill Kapogiannis: Thank you Bonita. I think again a very good question and it sort of articulates the breadth and complexity of the kind of research necessary in the ATN agenda. You know, the behavioral protocols we recognize do have a bit of nuance in how we approach the analyses, particularly, and I know that teams do at times engage more fully with their own. And, you know, at various degrees with analytic centers.

The way that the RFA is currently written the focus on the analytic activities is on the analytic center. Does that mean exclusively it has to be there, not necessarily. I think that as long as there is some latitude in the language of the RFA that allows for you to engage in discussions and planning and coordination with your analytic center.

So, to the extent that it makes sense for you to do certain, you know, exploratory, descriptive, lower-level analyses for example, you might be able to do that. But I think the way the RFA is written, and the way that folks are going to want to look at what probably their peers will be looking for is that focus on being, you know, the main focus being on analytic center.

Bonita Stanton: Thank you.

Operator: And again that's star one if you wish to ask a question. We'll go to our next question.

Sylvie: Hi. This is Sylvie again. So that makes sense on the analytic side, on the data kind of management side in the original ATN we kind of had some different approaches where some of it was some protocols were more centralized, some were more individualized, and I'm wondering if

there's sort of a strong preference either way or if we can make a case for, you know, whatever really works best for us?

Bill Kapogiannis: Sorry. I think again it's in this current design the intent is behind, you know, having coordination and collaboration between investigators and activities and synergizing as much as possible. Again we, you know, to the extent that makes sense that certain pieces stay within a team, a project versus a core. I think you need to work that out with your core leader, but I think that again, you know, I think we've kind of answered that.

Sylvie: So the more coordination the better? I'm hearing that. Okay.

Bill Kapogiannis: Exactly!

Operator: And again that is star one if you wish to ask a question. We'll now go to our next question.

(Marvin Belzer): Hi Bill. This is (Marvin) again. A question about the U-19s:does NICHD have the ability to fund some of the RO one's but not all of the RO one's and the successful U-19?

Bill Kapogiannis: Thanks (Marvin). I think again there is a potential for something of that type of scenario to play out. Again it's not something that we a priori want to count on, but if it is something that makes sense for program priority and those elements that I described earlier about geographic population focus, et cetera that makes sense, then as an institute, as an agency we will take all of the considerations of the peer review and all of those elements as well and decide and do what is best. If that's what we need to do then we will.

So, again there'll probably be some FAQs, at least one or two that'll be on the Web site alluding to this.

Operator: And again I have no other questions in the queue at this time. If you'd like to ask a question it's star one to ask a question. And it appears we have no questions in the queue.

Bill Kapogiannis: Well, I think since it appears that there may not be any further questions, I would like to take this opportunity to again thank all of you for your interest and devotion to the agenda, advancing agenda on youth and HIV, addressing youth and HIV in this country.

And I would again encourage you to visit the Web site www.nichd.nih.gov for the Webinar, the FAQs, and the transcription of this call so that you can use it for any of your needs. Thank you again. And have a wonderful rest of the day.

Operator: And ladies and gentlemen that does conclude today's conference call. Thank you for your participation.

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