Cyberseminar Transcript

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Session: HSR&D Innovation Initiative Program RFA (Planning/Start-Up Funds)

Presenters: David Atkins, MD, MPH; Courtney Paolicelli, DrPH, RDN; Naomi Tomoyasu, PhD

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Molly: And without further ado, I would like to introduce our speakers today. Joining us we have Dr. David Atkins. He is the director of HSR&D. Also joining us is Naomi Tomoyasu. She is the deputy director of HSR&D. And finally, in case you have not been introduced, I would like to introduce Dr. Courtney Paolicelli. She is a new scientific program manager with HSR&D. Earlier this year she came to the VA from the U.S. Department of Agriculture, and she will serve as a scientific program manager for projects by this new RFA. She has a clinical background in dietetics, diabetes education, and health education, and currently serves as a dietician in the U.S. Army Reserves.

I would like to thank our presenters for joining us. And before I turn it over to them, we’re going to go through a couple poll questions just to get an idea of who is in our audience. So just one second and I will pull that up.

All right. So as you can see on your screen, we have the first poll question. We’d like to get an idea of what is your primary role in VA. The answer options are student, trainee, or fellow; clinician; researcher; administrator, manager, or policymaker; or other. And please note if you are selecting other, I will put a more complete list of job titles in our feedback form at the end of the presentation, so you might find your exact job title to click there.

This is great! We have a very receptive audience; 85% have already given their responses and more are coming in, so I’m going to give you just a second to finish that up. Okay, biggest response rate to date. Thank you everyone. I’m going to close this out and share those results. As you can see, 2% of our respondents selected student, trainee, or fellow; 6% clinician; 66% researcher; 19% administrator, manager, or policymaker; and 6% other. Before I move on, did any of you have any commentary you’d like to make on that?

Dr. David Atkins: No. Glad to see that we’re drawing in some people outside of research who may be enticed by this to do research.

Molly: Excellent. Thank you. So we’re going to move on to the second poll question. We would like to get an idea of have you previously been funded by an HSR&D award? The answer options are yes, via Investigator Initiated Research known as IIR; yes, via pilot project known as PPO; yes, via Career Development Award known as CDA; no, I haven’t received HSR&D funding; or I don't know. And this is a question where you can select all that apply, so feel free to select more than one option if that applies to you.

Once again, we’re getting a lot of quick responses, so I will close this out in just one moment. Okay. Looks like the answers have stopped streaming in, so I am going to close out this poll and share those results. As I mentioned, this was select all that apply, so we will have over 100%. The first answer option, Investigator Initiated Research, 40% selected that; 16% selected PPO; 15% CDA; 46% have not received HSR&D funding; and 2% aren’t sure. Before I move on to the next one, do you have any commentary on that David, Naomi, or Courtney?

Dr. David Atkins: No, it looks great. We’re glad we’re attracting some people who may see opportunity that they didn’t see in other mechanisms.

Molly: Wonderful. Well, this is the last poll question at this time before we get going. It’s a pretty easy one, yes or no. Are you currently affiliated with one of the VA HSR&D Centers of Innovation, known as COINs. Please just select yes or no. Looks like about 80% have responded, so I’ll give people just another second or two. Okay, I’m going to go ahead and close this out. Looks like we are just about split two-thirds and one-third. So 65% selected yes and 35% selected no, so thank you again to those respondents.

Now, David, I would like to turn it over to you.

Dr. David Atkins: Thanks. I’m delighted to be able to kick off this discussion. This has been an issue that has been percolating in research for a number of years in the fact that we were seeing our research proposals come in and realizing that a relatively small proportion of them were making any real bold steps to try to propose things that were a different way of approaching our problems. I think we’ve made important contributions through incremental improvements through research, and I don’t mean to diminish it, but I think many people have recognized that there’s a rift that our peer-review mechanisms can be a barrier to innovation.

This initiative really represents the results of more than a year of effort by my colleagues to see what we could do to address what we thought was a gap. I think a clear signal of the gap was the fact that the other parts of the VA were establishing their own innovation centers, which to us were a statement that somehow we weren’t providing what we thought could be a product of research, which is the kind of innovation that our leaders or our program leads were looking for. This is an attempt to try to reclaim some of that ground. What you’ll see as we lay this out is that the very process of getting more innovative ideas is going to require us to be more innovative in what we’re looking for.

We’ll be walking you through the details of the solicitation, and I’m just going to emphasize that what we’re, recognize is that one reason we don’t get more innovative ideas is that they can inherently look riskier, so that our current funding mechanisms, peer reviewers may be reluctant to commit four years, a million dollars of funding to something that doesn’t have a long track record, that is proposing to do something that’s tough to do. So that gets more weight than the fact that if they can pull it off it would actually be really some, a substantial contribution.

We’re looking for ideas that really look different than the typical research proposals that are proposing to do something that’s older, that’s reaching a little bit higher, even if at, what comes along with that is a somewhat higher risk of failure. So you’ll be hearing about how we are phasing the support for these to allow us to make multiple small bets, recognizing that many of them may not pay off, but in the hopes that the ones that do pay off will actually give us something that looks different than our usual awards.

So this is your chance, and I think what we’re seeing in the polls reflect what we were hoping, that we’re getting researchers who aren’t at our largest research centers. We’re getting people who haven’t been funded before. And we’re getting even people who may not see their primary identity as researchers, who are at least coming to learn about this. I’m going to turn it over to Naomi Tomoyaso, who really has been spearheading this effort with some colleagues in the field to walk you through some of the details of this.

Dr. Naomi Tomoyasu: Thank you, David! Okay, I think pretty much, David, you have described the intent of this HSR&D Innovation Initiative RFA. And as you know, this is phase one, the planning phase of this Innovation Initiative. As David mentioned that we’re trying to get innovative, high-risk, high-impact research that provides, that will lead to meaningful real-world transformations and also contribute significantly to the field of health services research. What this RFA will not do is is to support research that is not typically funded through the established or traditional IRR [sic] mechanism where innovative high-risk ideas may not be favorably scored. So this is an opportunity for all of you to think big and to think bold. Next slide please.

Okay, David mentioned that this was a team effort. I think it took a village to be honest with you, and it took almost a year. It’s a process that I think it started off when I first came here about two and a half years ago, and I visited, started visiting the COINs. One of the questions that I consistently asked was, well, what would you like from HSR&D in the way of new funding mechanisms? And consistently, and it sounded like they were all thinking along the same lines, that they really, really wanted something like an RFA, something like an RFA where they would essentially be able to submit really high-risk, high-impact ideas and that we would be providing them a little bit more support, a little bit more time to think these things out. So that sort of was the idea, the premise that came to us about two and a half years ago.

Fortunately, when I got back, everybody loved the idea. And we were fortunate enough to come, well, meet Dr. Jolie Hahn of the Tampa VA. We were able to recruit her to essentially find out what in the field, how did the field define innovation, and what might be some of the suggestions that they could provide to us in the way of developing an RFA that would then elicit the big bold ideas that were high-risk but high-impact studies.

So what Dr. Jolie Hahn did was she essentially conducted, using a rapid mixed-method approach, she interviewed a lot of people through five focus groups, 10 individual interviews, three follow-up interviews. The participants that recruited for these interviews came from various fields, disciplines; 12 were VA scientists, three were from VACO operational administrators, one from the VA Center for Innovation as David mentioned, one from the Diffusion of Excellence. She also interviewed the scientific program managers from HSR&D and RR&D, and there were nine innovation experts also from the Institute of Advanced Discovery and Innovation who specialize in innovative studies and ideas. We also recruited two NIH program administrators who also had conducted and released innovation-related grants. And of course, we also did an environmental literature scan.

All of the interview results, all of the literature scan results were compiled into the white paper, and we also sent that white paper out to all of the COIN directors. They provided us additional feedback in terms of the ideas that we had in the way of coming up with a good Innovation Initiative RFA that would elicit high-impact, high-innovative studies. I want to thank Dr. Jolie Hahn for her efforts, and we will be coming up with an opinion, well, a policy paper shortly so everybody can read that.

So what were the results of also this qualitative interview and all of the work that Dr. Hahn did? Well, we found that people had various definitions of innovation. People thought that innovation was essentially creating or adopting new strategies, theoretical models, research methods from other disciplines. It also involved novel sources of data from new insights to enable new interventions. Some of our policy folks who were interviewed said that innovation could be defined as eliminating longstanding regulatory or policy obstacles. Our clinical partners said that innovation could be developing new partnerships, finding new ways of engaging hard-to-reach patients, and essentially, of fundamentally finding new ways to deliver established services. Of course, our implementation scientists said, well, you know there’s always room to find innovative ways of implementing or scaling current interventions that are promising or successful.

Another characteristic of innovation, based on all the interviews that were conducted, many people thought that innovative ideas pose higher risk, more so than traditional risk, but in return they offer greater rewards or earlier payoff. They often are associated with less pre-existing or no existing data to support the idea, and hence the concept that it’s higher risk. It can also be disruptive, but then it offers, innovative ideas can offer opportunities for different standards of practices.

They also mentioned that innovative ideas can be novel concepts, approaches or methodologies or interventions or adopting an existing process or a product in a new or unusual way. And one important consistent feedback that we got from all those that were interviewed, that innovation results in impact, has to result in impact. It can address problems in terms of prevalence, severity, urgency, or cost. It has the potential, it should have the potential to produce significant lasting changes. And innovative ideas have to have a broader goal, broader impact in terms of changing VA healthcare systems rather than focusing on specific sub-populations. Next slide.

What do we, what does HSR&D hope to achieve through this innovation RFA? We’re hoping that through, by supporting seeking high-risk, high-impact ideas that we can achieve major practice or health system transformation, not incremental changes. We hope to get larger impact versus modest changes in clinical or population health outcomes. And we want to have improvements that have a broader impact on and are applicable to the general population. And obviously because we are HSR&D, we want to move research in this area in new directions.

We’re also interested in developing technological advances or applying new technologies to new areas. We’re also interested in novel methods for organizing, financing, or delivering health or other social services for Veterans and their families and caregivers. And of course, we want to implement these promising or innovative ideas and scale them up.

We are, again, I want to stress this again and again. HSR&D is not interested in one-off studies that propose testing new technologies in well-established areas. So for example, we do not, although it might be interesting, we’re not interested in, let’s say, another application of a smart phone relative to weight management, something like that. They are important studies, but they’re probably better going through the usual SMRB route. And we also do not want technologies that will require FDA approval because of the time constraints.

Where this RFA also focuses on just five, the top five highest priority areas for VHA, VA. And the five topical areas are suicide prevention, opioid misuse/pain management, access to quality care, PTSD and TBI, and long-term care services and support.

We had to, it would have been great if we could have expanded the priority areas to other topics. We don’t mean to minimize the other topics. But because this is the first time that we are doing this, there’s a sense of urgency to accelerate innovative research in the highest priorities, and we are somewhat limited in funds. We’re not the Gates Foundation or NIH, so we started off with these five areas. In the future, if it works out, I think that we will be thinking about expanding to other topical areas.

Again, what we want to do is to stress collaboration with our VA operations and clinical folks as well as our non-VA entities. I know that many of you are already collaborating with our VA program offices, VISN leadership, other innovation groups across the VA, and many of you also are collaborating very closely with non-VA entities, other federal agencies, NIH, CDC, HRSA, etc., and other health systems. We encourage you to continue collaborating for this RFA.

So I’m going to pass this over now to Courtney who will describe the nitty-gritty components of how to apply for this, when the deadlines are, and then at the end she’ll try to address some of the questions that were submitted earlier and then address new questions that may be arising during the Cyberseminar.

Dr. Courtney Paolicelli: Great. Thanks so much, Naomi. I want to talk a little bit about this phased approach that we have for our Innovation Initiative program. So the RFA that we have released is for Phase 1, and so for this first phase the application is basically, the big chunk of the application is going to be this three-page concept paper or the three-page research plan. I’ll talk a little bit more about that here in just a couple of minutes. The number of applications that we’re planning to fund through this particular RFA is going to be up to 10. We’re also looking at a shorter duration than for our normal IIRs here at HSR&D. The duration of this first phase is going to, or the planning phase, is going to be up to 18 months, and the funding amount is going to be up to $200,000 per proposal. We’ll talk about the evaluation process for this first phase in just a couple of minutes.

But I just want to contrast this first phase with Phase 2, which will come after, obviously, the initial planning phase. So for the projects that are successful in receiving awards for Phase 1, those up to 10 projects will be eligible to compete for Phase 2. The application process for Phase 2 will include a full proposal as well as a full review that’s akin to the typical review you see for HSR&D IIRs. The plan is currently to fund up to three full proposals, and those proposals that are awarded for Phase 2 will be funded for up to five years in duration and they will receive up to $500,000 per year for those five years.

So again, the purpose of today’s Cyberseminar is to talk about this initial or the Phase 1 RFA, so we’ll go into a little bit more detail. But we did want to distinguish between these two phases just so everyone is aware.

Dr. Naomi Tomoyasu: And if I could add just one point. Phase 1, the planning portion, can last up to 18 months, but we’re encouraging folks to start applying in the 12th month so that they still have six months left of the planning phase. But they should apply for the IIR, the full proposal, because we don’t want you to have a gap in funding.

Dr. Courtney Paolicelli: Great. Thanks, Naomi. Okay, so I want to just talk a little bit more about the review process for this RFA. This process only covers, again, Phase 1 of the Innovation Initiative. Again, Phase 2 will have a different review process.

So as part of Phase 1, the research plans that are submitted will be limited to three pages. And please note that you may hear us refer to this section as the three-page concept paper. That’s the same thing as this three-page research plan. This research plan or concept paper will include the requirements outlined on pages 12 and 13 of the RFA, and the required sections include your project title, about one-half of a page for your aims or objectives, one to one and a half pages of the specific questions to be addressed in your proposal, and then a one-page description of the activity. Please note that this last section, the description of the activities, includes a timeline with brief descriptions of the specific activities that will be conducted during the planning or start-up phase to test the innovation research idea.

Each three-page research plan or concept paper will be reviewed based on the innovativeness of the research idea and the potential impact of the proposed research. These research plans or concept papers will undergo blinded reviews to reduce any biases or conflicts of interest during the Phase 1 reviews. As the planning phase funding will undergo an anonymous review, the names of the investigators, institution, or other personally identifiable information must be excluded from your three-page research plan or the application will not be accepted. We will be enlisting the help of a third-party contractor to ensure all research plans have identifying information removed before they are sent to the reviewers.

I want to note here that it’s only the research plans that have to take out identifying information. It’s okay to leave in identifying information in sections such as your proposed budget. Only, again, the three-page research plan has to have the identifying information removed. After the scientific review, there will be an administrative review, and then right now we anticipate making our award decision by April of 2019.

Okay, so you may be wondering with such a unique RFA who are we going to get to sit in on our review panel? Well, because we’re really trying to go outside of the box here, we’re going to be recruiting small specialized panels with reviewers of diverse backgrounds. We’re really recruiting folks who are experts and champions of innovation. These are the big thinkers who can help us move outside our comfort zone and push our research boundaries.

We plan to recruit some folks who are in the VA system, but we’re also planning to recruit non-VA innovators from academia, other federal government agencies, engineering, and information technology. We’re also planning to recruit folks from private industry who have an innovation track record. We feel that gathering a review panel with this kind of makeup will help us objectively rate the applications we receive and assist us identifying the most innovative and potentially impactful project proposals.

And what might some of the questions our review panels might ask? Well, some of those questions are outlined here on this slide. I’m not going to read through each of these questions. You can find them in section five on page 21 of the RFA, but just to point out a few that might be used to gauge the innovativeness of the proposals, reviewers might ask questions such as does the proposed work challenge current clinical practice paradigms by utilizing a novel approach, or will the proposed work contribute to an area of practice or science where the field is ready for a change? In addition to critiquing proposals for innovativeness and of the proposed research and strategies, reviewers will also critique the proposals for the impact of the proposal innovation.

Now on page 18 of the RFA you’ll find Table 5, which is our table of deadlines, award, and review dates. As noted here, we released the RFA last month and we’re holding the Cyberseminar today.

I really want to highlight that our Intent to Submit window is coming up. It opens next Monday on October the 15th and closes on November 1st at 8 PM Eastern Time. So if you’re thinking of submitting to this RFA, which we sincerely hope you will, you’ll need to submit your ITS by November 1. Instructions for the Intention to Submit are noted on page nine of the RFA, and compared to our normal HSR&D ITS for merit proposals and pilot projects, this is a much simplified version of the ITS. So again, refer to the instructions on page nine of the RFA for specific information.

Dr. Naomi Tomoyasu: Could I also add…

Dr. Courtney Paolicelli: Sure.

Dr. Naomi Tomoyasu: Yeah, the ITS, that’s mandatory and primarily it’s required because we wanted to get a head count and the number of people who would be applying for the five priority areas. But you don’t need to blind them. What we’re hoping to do is to have the contractors do the counts and then they will provide us with the numbers.

Dr. Courtney Paolicelli: Thank you. Thanks. Okay, and then this slide is just the second half of Table 5. When submitting your full proposal, you’ll just need to make sure that you submit no later than December the 12th. Then again, our plan right now is to have our Scientific Merit Review Board, or a SMRB, meet to critique the proposals in late February or possibly early March. And this is going to depend on our reviewer and administrative availability. Following that will be our administrative review, and then again, the awarding of funding in April of 2019.

I know we’ve discussed a lot of information over the past half an hour, so if you’re confused or don’t understand something, never fear, we’re always here and you can always email your questions to our scientific review inbox at the address that’s listed here on this slide, and we will answer your question over email. And thank you to those of you who submitted questions prior to today’s Cyberseminar. We’re going to go through a few of those in just a couple of minutes. But before we do that, I want to turn it over to Molly, who has two more polling questions that we want to pose to everybody. So Molly, if you can take control and ask those questions, that would be great.

[Pause 30:17 to 30:35]

Molly, are you on mute?

Molly: Thank you. My microphone decided to stop working, but we do have the poll question up. Do you think you will be applying for funding under the new Innovation Initiative RFA? And about half of our audience has voted, so we will give people a few more seconds. Okay, it looks like just about 80% have responded, so I’m going to take just a moment and close that out and share those results. As you can see, 57% selected yes, 10% selected no, and 34% selected undecided. Do you have any commentary or would you like me to move on to the last poll?

Dr. David Atkins: No. No.

Dr. Courtney Paolicelli: No. That’s helpful. Thank you.

Molly: All righty, so for our final poll question, we would like to get an idea if you are applying for funding under the new Innovation Initiative RFA, how many applications do you anticipate submitting? One, between two and three, or more than three. And responses are coming in. We do have a lot of people writing in asking how many people are in this session. Just so everybody knows, it’s just over 180 attendees.

Okay, and it looks like everybody has finished responding that’s going to respond to this one, so I’m going to close this out and share those results. Eighty-four percent selected one, 14% selected between two and three, and 2% selected more than three, and that is of the audience subset that said they will be submitting. So thank you very much.

Now I will turn it back over to you, Courtney, for the screen share and the questions that were submitted ahead of time. There you go.

Dr. Courtney Paolicelli: Great. Thanks so much, Molly. Before we get into the Q&A with the attendees on the line today, there were a couple of questions that came in prior to the Cyberseminar that we wanted to address because we felt like these were clarification points that we wanted to make sure everybody received.

In one of the questions it asked about, or the attendee asked in the Innovation Planning Grant RFA is says that start-up activities would be IRB exempt. And then she was just asking in particular would consulting with Veterans and providers about ways to adapt an innovation to the VA be considered IRB exempt; there will be no PHI. So on page 13 of the RFA we say that activities conducted during the planning phase should not require IRB approval. However, we want to note that if applicants wish to perform activities which require IRB approval during the planning phase, they may do so just as long as these activities can be completed within the planning phase timeline. Then, of course, we always want to note the applicants should always consult with their local IRB to determine what activities would be considered IRB exempt.

There’s kind of two things here, one being this issue of getting IRB approval as part of the activities that are being conducted during this planning phase, and as Naomi mentioned before, we’re really wanting folks to get their activities done in closer to a 12-month timeline because we don’t want to have a gap in funding between when you’ve got the funding for the planning or the Phase 1 and are applying for Phase 2. We know that IRB approvals can take some time, so it’s just important to be mindful that if some of the activities you’re proposing will require IRB approval, we just need to be mindful of how much time that’s going to take and make sure that the timeline is going to be feasible or realistic. And then again, we at HSR&D don’t make the determination as to what is IRB exempt. That’s something that you’ll need to consult your local IRB to determine.

There was also a question regarding the use of preliminary data. So the question came in and it was one of the two main criteria is the impact the strategy or innovation could have. However, no preliminary data are supposed to be included. We have big data showing how big the impact, or we have preliminary data, rather, showing how big an impact would be. Are we only supposed to use data from other published studies to demonstrate impact? Although it’s not required, preliminary data may be used to justify the potential impact of the innovation. However, I want to stress preliminary data should not be used to provide background or rationale for the proposed strategy or intervention.

So again, if you have some preliminary data and you want to use that to justify the potential impact that you think your innovation would have, that would be fine. But again, we don’t want to be using preliminary data to provide justification or rationale or background for the proposed strategy or intervention.

Molly: Courtney, I’m just going to interrupt real quick.

Dr. Courtney Paolicelli: Sure.

Molly: One of our fellow Central Office colleagues wrote in and wanted to mention that you cannot do IRB activities with planning funds. That is all.

Dr. Courtney Paolicelli: Okay. All right, thanks. Then there was also one more question about whether or not it would be okay for an investigator to submit, oh…

Dr. David Atkins: Go ahead.

Dr. Courtney Paolicelli: Would it be okay for an investigator to submit on a similar topic area to both the Innovation RFA as well as the traditional HSR&D IRR [sic] in December? And so yes, investigators may submit on a project. Yes, investigators may submit a project on a similar topic to both the Innovation RFA and to the traditional HSR&D IIR in December just so long as the aims of those two projects are different.

All right. And again, those were just some of the initial questions that came in before the Cyberseminar today. So without further ado, Molly, do we have any questions that are coming in from the chat box? Would you like to go ahead and facilitate some additional Q&A?

Molly: Yeah, we have about three dozen questions that have come in, so we will go ahead and get right on them. For those of you that joined us after the top of the hour, please note that you can submit your question or comment using the control panel located on the right-hand side of your screen. Down towards the bottom there’s a question section. Just click the arrow next to the word questions. That will expand the dialogue box, and you can submit question or comment there. We are going to jump right in, in the order that they are received.

Before I do, I just wanted to add in one more correction from when we were doing acknowledgements. Pardon me just one second. Kathy Plojack [phonetic 38:23] just wanted to acknowledge that there is a misspelling on the call, I’m sorry, on the slide, and it was Jolene’s [phonetic 38:31] name and also one other person. I think it was just Jolene’s name, but we just wanted to shout out, and we’ll correct the slides before we upload them again. Thank you.

The first question is for the ITS, what information is to be included in the ITS regarding the research plan?

Dr. Courtney Paolicelli: That is a great question. Before I answer it, again, I’ll note that the ITS is described, or all of the instructions for the ITS are described in the RFA on page nine. And so for the ITS, there’s actually not a research plan that’s going to be included. As I mentioned, the Intent to Submit is going to be way more simplified than the normal HSR&D ITS. In this case, really the only thing that we’re going to be looking for in the ITS is going to be which one of the five priority areas your project is going to be addressing. So you’ll have to select one of those five priority areas from a drop-down list. But other than that, there won't be a long narrative or anything of that nature that you’ll need in the ITS. But again, those instructions are on page nine in the RFA.

Molly: Thank you. And that leads to a great follow-up question. Where can we find the RFA?

Dr. Courtney Paolicelli: The RFA is posted on, it’s posted through the HSR&D website and…

Dr. David Atkins: Yeah, you have to be on the intranet side of the website, so you can't access it from outside. But if you go to the internet version of the website, it’ll tell you the link that you then have to cut and paste to take you to the intranet. Since only VA investigators can apply for these awards, we don’t make our RFAs visible on the internet site.

Dr. Courtney Paolicelli: Yeah, and if somebody is having difficulty finding it, they can shoot us an email at the or [vhacoscirev@va.gog](mailto:vhacoscirev@va.gog) email address that’s posted here on this slide, and we can send them the link.

Molly: Thank you. So the next question, and keep in mind a few of these came in pretty early on in the presentation, so if you did cover it, you can mention that and just give the abbreviated version. This is a comment. Please, in the future, don’t just rely on COIN directors and presumably affiliated investigators for interviews or input into important decisions such as these. This excludes all investigators not at COIN centers. You can just as easily go to the ACOS/R and ask for their opinions as this is much more representative sample than COIN directors alone. Thank you.

Dr. Courtney Paolicelli: Thanks for that comment.

Molly: Yeah. What do you require for collaboration within the planning grant? Do we need letters of support from VA program offices?

Dr. Courtney Paolicelli: Another really good question. For purposes of this application, we are not asking for letters of support. But forming partnerships and collaborations as part of the planning activities or as part of the activities board that’s planning this planning project would be appropriate. We anticipate that the successful projects will have a number of collaborators and partners working on the innovative strategy or the innovation project.

Dr. David Atkins: Yeah, we didn’t want, we’re expecting that we may elicit hundreds of ideas. We didn’t want all of those investors besieging a small number of partners at this stage. So we’re hoping that the planning process would be the point at which those projects that are selected would then build their partnerships.

Molly: Thank you both. Okay, the next question. If you want studies to be applicable to “the general population” and to have broad impact across VA, aren’t some of these focus areas contradictory to this? For example, TBI/PTSD seems to be a specific sub-population. I’m a bit confused about whether you want proposals that are focused in certain areas or not.

Dr. Naomi Tomoyasu: So…

Dr. Courtney Paolicelli: Go ahead.

Dr. Naomi Tomoyasu: Yeah, we do want all of the submission that are provided to us to focus on the general population. TBI/PTSD is a special case. It is actually one of the top three priorities for the VA and that’s one of the reasons why we included that. But for the other four topical areas, they should be applied to the broader population and not to a specific sub-population.

Molly: Thank you for that reply. The next question we have: Does access to quality care also include providing care for Veterans residing in rural locations?

Dr. Courtney Paolicelli: Yes, absolutely. Again, another great question. This is, when we talk about access to quality care, we’re purposely trying to keep this broad. So this would be, if that was your selected topic area, you would just want to articulate the rationale on how your project would fit into that priority area in your three-page research plan or your three-page concept paper. Thank you.

Molly: Thank you for that reply. The next question: You mentioned that you are not looking for proposals that require FDA approval. If we are developing a device that down the road will require 510(k) FDA approval, are we eligible to submit the grant?

Dr. David Atkins: I would suggest that you contact us individually. In general, we are not, those kinds of studies usually come through our clinical sciences research program and are usually beyond what we’re looking for here. But depending on what the nature of the innovation is and whether it’s feasible to collect the kind of data you need in the duration of this proposal, my guess is it probably won't fit, but let’s have an offline discussion.

Molly: Thank you. This was a clarifying question that came in fairly early. Can you please repeat the split? So I’m not sure if that was a funding split or they can write in for further clarification or you might know what they are referring to.

Dr. Naomi Tomoyasu: Yeah, can you get some more clarification on what they mean by split?

Molly: No problem. It was from a slide and we will wait for that person to write back in and then we will re-visit that question.

Dr. Naomi Tomoyasu: Yeah, and maybe as you, if I could take just a brief moment, 15 seconds just to clarify the question regarding the comments regarding planning funds used for activities that, not being able to be used for activities that require IRB, actually this is, I believe 824 money, it’s research money. So if you plan on activities that don’t require IRB, then you don’t need IRB, say, for QI purposes or whatever, although you should consult with your IRB, local IRB. But if they do require, the activities that you’re planning during this planning phase does require IRBs, then by all means, you should. Now we’re saying that probably in the first year, you probably will not have time to pull together the package for the IRB and get IRB. So most likely the majority of your activities are going to be, are not going to require IRB, but…

Dr. David Atkins: And it relates to our ability to get money to you quickly. The idea is we want people to start working on these activities. When we talk about planning funds, those are things that we can send out without having the IRB approval in hand. If there’s a component that is going to require IRB, you need to spell that out carefully so that we can hold any of that funding until the IRB approval…

Dr. Courtney Paolicelli: Clears.

Dr. David Atkins: Yeah. So our discouraging IRB approval is just we want you to be able to use the full 12 months so that then you have accomplished what you need to then support a full proposal for the larger funding, and we’re just, in most cases, IRB components will slow that process down.

Dr. Courtney Paolicelli: Right.

Molly: I really appreciate you clarifying that because we had several people write in asking for clarification too. So to those people that submitted the question about that, please note that I am not going to read through all because I think that sufficiently explained it. If you do not feel it sufficiently explained it, then you can write in again. Otherwise, I will be skipping over the questions about that.

The next question: Do names of partners need to be blinded in the research plan to include, or I’m sorry, do names of partners need to be blinded in the research plan too, including non-VA organizations?

Dr. Naomi Tomoyasu: Okay, we want, the blinding component is a challenge, and I don’t think we’ll ever have it totally blinded. I understand that you will be working with partners, but we would like, we don’t mind so much the names of the offices, the partners that you will be working with, but please refrain from citing specific names within each of the offices.

Dr. David Atkins: Individuals.

Dr. Naomi Tomoyasu: Individuals, excuse me.

Molly: Thank you. How will you handle references? They often give away who is writing the proposal.

Dr. Courtney Paolicelli: Yeah, so the references are actually not going to be included as part of the three-page concept paper or three-page research plan that the reviewers are going to be seeing. So we’re still asking for you to include your bibliography and your references. However, that will not be something that’s shared with reviewers.

Molly: Thank you. And this next question you may have covered. Will investigators have the opportunity to revise and resubmit proposals based on reviewers’ critiques?

Dr. Courtney Paolicelli: So at this point this is the only RFA that we’re planning on posting for the Innovation Initiative. Unfortunately, we just don't know if we’re going to have the funds available to do this again. So there will, at this point there is no resubmission process. And I don't know if Naomi or David want to chime in anything additional.

Dr. David Atkins: We will see how this goes. It’s possible that six months from now we will re‑release this with a different set of priorities. It’s possible we’ll release it with a broad set of priorities, in which case we will probably be getting back to a limited number of people who didn’t succeed in the first round but who we thought had some potential. So right now, no promise, but possible.

Dr. Naomi Tomoyasu: It’s an experiment for us. Unless we get astoundingly innovative, impactful ideas, and we’re all hoping that that will be the case.

Molly: Thank you. This next question: What is meant by “high risk?” Expensive but may fail? Or does it have a broader definition?

Dr. David Atkins: I think when we, there’s obviously no definition of high risk and we don’t, it’s not a prerequisite of these proposals, but it reflects the fact that usually if you’re proposing something that is not built on a long track record, it has a high, there’s less to go on in terms of predicting how likely it is to succeed. So the premise is that to really make large contributions you need to sort of reach farther, and that is inherently riskier than proposing something that’s a small incremental improvement in a very established area. So it’s high risk in the sense that it may be doing something we haven’t done before in VA, and so we don’t have a long track record. It may be high risk because it’s new and there isn’t yet preliminary data, which will accumulate in the course of a longer project. It may be dealing in an area where there have been regulatory obstacles that have sort of deterred people from working in this area but that people think they can overcome, or getting datasets that have never been accessed before for these purposes. So I would say the main component of high risk is just there’s less, we’re not looking for things where we have enough preliminary data that we can really predict the likelihood of success.

Molly: Thank you. I’ll keep going along. Does the complete team need to be included on the ITS or can you add people to the project after the ITS is submitted?

Dr. Courtney Paolicelli: Yeah, the ITS is pretty simplistic, so there’s not going to be a requirement to include all team members on the ITS.

Molly: Thank you. Are university affiliates allowed to be PIs on these grants?

Dr. David Atkins: Eligibility is the same as for other VA research. The PI has to have a five-eighths appointment.

Molly: Thank you.

Dr. David Atkins: [Unintelligible 55:01].

Molly: If the reviewers are at least in part from outside the VA and yet we are asked to apply under five areas unique to the VA, how will the non-VA reviewers know what is innovative for the VA?

Dr. Naomi Tomoyasu: Well, that’s a very good question. That’s why what we wanted to do was to have a mixture among our reviewers of VA, mostly VA, as well as non-VA folks. What we have found from our observations from our SMRB as well as from the interviews that were conducted, many of the participants suggested having outside folks because they could bring a broader, more, a newer perspective. Hence, I think the combination of VA reviewers as well as non-VA will probably be the best in terms of not only bringing in the information, the experiences of the VA, but also newer perspectives.

Molly: Thank you. So we did have numerous people write in this same question. We are getting through the questions quite quickly. Three people wrote this in, so I’m just going to paraphrase it. Can a project address more than one priority area? Somebody else wrote it as what if your proposal addresses more than one priority area.

Dr. David Atkins: Sure.

Dr. Courtney Paolicelli: Absolutely.

Molly: All right. The next question: Can you please expand on the issue of not using preliminary data to provide rationale? In some cases where a research topic is new, the preliminary data may be the only background info to the field. Oh, I’m sorry, info in a new field.

Dr. Courtney Paolicelli: Yeah, so this, and please, for this question if somebody has a specific concern about preliminary data and whether or not they can include it in their research plan, feel free to shoot us an email and we can have a one-off conversation. But in general, we are saying that if you want to include preliminary data to justify the impact you suspect your intervention will have, or your innovation, rather, will have, then that’s fine. We just don’t want preliminary data supporting the, to support the actual description of the innovation strategy or the innovative intervention. But again, I know that this, there is nuances and I want to make sure that we can help individuals that have preliminary data figure out whether or not it’s appropriate to incorporate into that their proposal. So feel free to shoot us an email and we can have that conversation.

Dr. David Atkins: I think the main reason we included that language is we recognize that there are going to be some innovative ideas that don’t yet have preliminary data. So we didn’t want the expectation to be that all the proposals that came in had to have worked out all of these issues and generated preliminary data. We thought that would narrow the breadth of ideas. So we don’t want to penalize people who happen to have preliminary data, but we also didn’t want to make that an expectation because some people may have ideas that, you know, their planning phase is going to show whether this idea, which sounds great, is actually viable. We didn’t want to give the advantage all to those groups that had already worked those things out. So I think, as Courtney suggested, contact us directly and we’ll find ways that, you know, so that you’re not penalized for the fact that you happen to have some preliminary data.

Molly: Thank you. We are at the top of the hour, but we do have about 10 pending questions. David and Naomi and Courtney, are you able to stay on and answer them so that we can capture them in the recording for the viewers?

Dr. David Atkins: Sure.

Dr. Courtney Paolicelli: Sure.

Molly: Thank you. So if any of our attendees do need to drop off, two quick notes. Number one, this session has been recorded and you will receive a follow-up email leading to the recording in just two days from now, so feel free to pass that along to colleagues you think might be interested in this topic or that weren’t able to attend live. Furthermore, if you are exiting the session, please wait just a second while the feedback survey populates on your screen and give us some feedback. It’s just a few short questions. So I just want to make sure we capture your feedback and can improve this presentation for the future as well as the program as a whole. So thank you.

And we’ll get right back to the questions. When do you anticipate funds to be available?

Dr. Naomi Tomoyasu: Well, available funding, when can people get started? We’re hoping, I think we had listed April 1st. I will be honest with you. It will be in April. Don’t hold us to the April 1st deadline, but it will be sometime in April. And that depends on, as Courtney mentioned before, that we’re trying to work out some of the scheduling for the reviews because we want to synchronize it with the regular SMRB, the merit reviews. But it may end up that we have it at a slightly different time. But the deadlines for the ITS and the deadline for the three-page research plan still holds.

Molly: Thank you. The next question: Would DoD partnerships be of interest? Would innovative data/statistical methods be of interest?

Dr. Naomi Tomoyasu: Yes. I think one of the areas that, innovative ideas that we mentioned in the RFA, is that if there are new data sources, new methodological approaches, new statistical approaches that have not been done before that would actually advance the field or identify new areas, gap areas, then by all means, please submit those.

Molly: Thank you. Is it possible to get a preliminary review of whether a concept will meet the special focus areas?

Dr. Courtney Paolicelli: Yeah. I think that if folks are concerned that their proposal may not meet one of those areas, they’re more than welcome, again, to send us an email, and we would be happy to vet that. Yes.

Molly: Thank you. The next question: If 10 projects will be funded in five target areas, is the goal two projects per area?

Dr. David Atkins: It’s not exactly that. I think we’ll strive for parity, but if the best ideas, if it’s three and one, I think we would like to have at least one…

Dr. Courtney Paolicelli: Yeah.

Dr. David Atkins: …in each of the five areas. But there may be two, there may be three.

Molly: Thank you. Would proposals from VA postdoctoral residents be considered or does the PI have to be a full-time VA employee?

Dr. Courtney Paolicelli: I think, yeah, these are…

Dr. David Atkins: Yeah. There wouldn't be…

Dr. Courtney Paolicelli: Yeah, we still have the same requirements as for our regular pilot projects and merit awards.

Dr. David Atkins: Yeah, you’d have to have a commitment of a five-eighths position for the life of the project. So if you are in a postdoctoral position but haven’t yet been, gotten a term appointment, you wouldn't be eligible.

Molly: Thank you. The next question: If community partnerships have been established and are currently being funded by other sources, should those sources and/or identified community partners be blinded in the application?

Dr. Courtney Paolicelli: That is a new one.

Dr. David Atkins: The main purpose of blinding is to avoid favoritism based on, more on individuals rather than…

Dr. Courtney Paolicelli: Organizations.

Dr. David Atkins: …organizations.

Dr. Courtney Paolicelli: Yeah.

Dr. David Atkins: Yeah. I think if it’s directly relevant to impact, then I think it can be, they can be included, but I would also encourage you to reach out in, directly because I could imagine some cases where it might run the risk of introducing bias, but I can also think of other cases where it wouldn't.

Molly: Thank you. Would quality care include care for Veterans’ family members? For example, spouses and children.

Dr. Naomi Tomoyasu: Yes, we included that.

Dr. David Atkins: Well, I guess only to the extent that they’re eligible for care from the VA.

Dr. Courtney Paolicelli: Yes.

Dr. David Atkins: So certain, under the Caregiver Act there are certain provisions that caregivers can be eligible for VA care. But we’re interested in innovations that’ll improve the care the VA is responsible for. And I think if it’s interventions for groups that the VA is not currently responsible for, but I would, sounds like another issue to probably clarify individually.

Dr. Courtney Paolicelli: Yeah.

Molly: Thank you. Regarding blinding, I can redact names and the center name. However, once we start talking about collaborative program offices, Congressional mandates of the center, etc., someone familiar with the center and investigators could piece together who it is from. Do you have advice on anything we can do other than redact names to ensure it is blind?

Dr. Naomi Tomoyasu: I think that’s about all we can do or that you can do. As I mentioned before, we’re trying to reduce bias on the part of the reviewers as well as us, but I don’t think that blinding, going to try but it’s not 100%.

Molly: Thank you. The next question we have: Is subacute care service considered as part of the long-term care service?

Dr. Courtney Paolicelli: Hmm. I think in that case it might be helpful for us to get an email with a little bit more of the…

Dr. Naomi Tomoyasu: What they mean by…

Dr. Courtney Paolicelli: Yeah, a description of the proposed activities and kind of go through it and make sure that it does jive with one of our priority areas.

Molly: Thank you. We’re getting down to the last few questions. Can funds be used for travel and for team meetings? I’m sorry, travel for team meetings.

Dr. David Atkins: Yes.

Dr. Naomi Tomoyasu: Yes. Yes. Anything that relates to planning, getting information that would inform the full proposal or study aims, etc. That would all be included. That would be covered.

Molly: Thank you. The next question: Should the Phase 1 concept paper detail plans for Phase 2? Are there standard funding restrictions? For example, no equipment.

Dr. Courtney Paolicelli: I believe, yeah, there’s, in Table 4 we detail some of the clarifications and instructions for budget items, so we talk about equipment in that table.

Dr. Naomi Tomoyasu: But let’s say that you’re interested in, I don't know, so in an interactive voice recorder, that’s, is that [unintelligible 1:08:02]. I guess that’s considered equipment. So I guess we have to get more information.

Molly: Thank you. And the first part, I’m sorry David, did you have something to add?

Dr. David Atkins: I don’t think your, the planning proposal needs to spell out all the anticipated budget…

Dr. Courtney Paolicelli: Right.

Dr. David Atkins: …issues for the full proposal. But there will be restrictions on what you can use the larger budget for, in terms of we can't fund IT...

Dr. Courtney Paolicelli: Right.

Dr. David Atkins: …equipment. There can be, depending on what it is in terms of the innovation, there may be ability to include some medical equipment or other equipment within the proposal.

Dr. Courtney Paolicelli: Right.

Molly: Thank you. The next question: You might have covered this. Can brand new investigators submit for this or only established independent investigators? For example, if we are clinicians and primarily focused on program development/intervention develop so far but have early data on a new intervention?

Dr. Courtney Paolicelli: No, you do not have to be a seasoned researcher. And that was one of the feedback that we received that innovative ideas can come from anyone. The only restriction is that you have to have five-eighths VA employment. When you, but we do encourage clinicians who don’t come from research to probably collaborate with researchers.

Dr. David Atkins: Yes. I would encourage, I think what you’ll want to do in your planning project is to build those connections. Obviously if these ideas went on for the larger, longer funding, as a clinician you’re going to be responsible for getting the protected time to actually be able to lead the project. So on the second phase of this, which is not going to be blinded, those will be questions that will be looked at very closely whether you have the ability and the time to lead a multi or much more ambitious project. But at this stage, you do not have to meet those requirements. But you should talk about how you’ll build a team that would be able to compete successfully for the second phase.

Molly: Thank you. I do just want to mention that the person asking for the clarification on what the split is, they did not write in for further clarification, so if they want that asked and answered, they can contact you offline. Furthermore, someone else wrote in about the preliminary non-published data and I instructed them to also contact you offline for case by case questions. And…

Dr. David Atkins: So in terms of those, Molly, just the split may have been about we’re giving 18 months of funding, but we are going to be asking for the full proposal probably somewhere around the 12th month so that it can be reviewed and decisions made before the end of the 18-month funding. So in the possibility that they were asking about sort of what the split is in terms of that 18-month period, I don't know if that’s what you meant. But we haven’t set the due date for the larger proposals, have we?

Dr. Courtney Paolicelli: No.

Dr. Naomi Tomoyasu: No.

Dr. David Atkins: No. But if…

Dr. Naomi Tomoyasu: It’ll be 2020.

Dr. David Atkins: Right.

Molly: Thank you. And the final question: Will the review panels be based on priority areas?

Dr. Courtney Paolicelli: It has to be based on the five priority areas. Is that what you mean?

Dr. David Atkins: The panel, so I think we will have some expertise representing the priority areas, but we are not, that will not be the only type of expertise. We’re not looking to create five different review panels based on the five priory areas. We’re looking for groups that will reflect some content expertise in those areas but also other expertise.

Molly: Thank you. Well, that does conclude the Q&A portion, but I’d like to give each of you the opportunity to make any concluding comments if you’d like. Since you’re all in the same room, I’ll let you shoot looks at each other and decide who goes first.

Dr. David Atkins: No, I don’t think we have anything other than that we’re excited by the level of interest in this. This is an innovation for us, which hopefully means this doesn’t have a high risk of failure…

Dr. Courtney Paolicelli: For us!

Dr. David Atkins: …that it does have a high potential reward. But we are assuming we will learn from this process, and we also assume that questions will continue to come up and we will be happy to try to answer them as quickly as we can if you send them into our mailbox.

Molly: Excellent. Well, I cannot thank you all enough for coming on and lending your expertise to the field. Many of our attendees have written in saying thank you so much for this. So just as a reminder, this session has been recorded. You will receive a follow-up email and it will be a copy of the handouts and a link to the recording, and in the coming days, a transcript will follow. So the Q&A answers have been recorded. So once again, thank you to our Central Office staff. Thank you to all of the support staff. Thank you to our researchers. And we are very excited to see what applications come in! And with that, I am going to close out the meeting. So for our attendees, once again, please stick around just a second while the feedback survey populates on your screen. Again, it’s just a few questions, but it will be incredibly helpful for us to review after this. So once again, thank you Courtney, David, and Naomi. Have a great rest of the day.

[ END OF AUDIO ]