Heidi Schlueter: Dr. Bever, can I turn things over to you?

Christopher Bever: Okay, thanks very much, Heidi. I'm Chris Bever. I'm the Deputy Chief Research and Development Officer for Investigators, Scientific Review, and Management, which is the new unit within the Office of Research and Development that will be essentially replacing the four services that many of you are used to.

I did an initial webinar on the changes that we're putting in place back in August. This is a follow-up to that where I'll repeat some of the information that was given there. Then there has been some additional refinements to things since then, so there'll be some new information as well.

I think, Heidi, you sent out the slide set that we had prepared already. Is that correct?

Heidi Schlueter: That is correct. Yes.

Christopher Bever: Okay. This slide set that I'm using today is updated, so you'll see some changes from what was distributed in this slide set, will be distributed to everybody after the meeting, just to clarify. There are going to be two slides sets going out. This one has a little two after its name to indicate that it was the newer one.

All right. Quickly, the agenda for today's meeting, introduction, why are we making the changes? What will replace the services? What are the changes to the application review process? What are the changes to the funding decision process? What is the new application review timeline? Then hopefully, we'll have some time at the end for questions.

I do have a hard stop at 1:00, so I won't be able to go beyond that. But I think Heidi should be able to get questions from the chat, if people want to put them in there, and I can work on them after this is over.

I wanted to start off with our 100-year anniversary, which is going to be next year. I think many people will be surprised that VA Research will have been around for 100 years next year. We have a record of really major accomplishment: the first randomized controlled clinical trial in the United States, I think of Streptomycin for TB, the cardiac pacemaker, the first liver transplant, the Seattle foot, the Deka arm. Then we have multiple global Nobel laureates; two of them shown here.

We have a long and successful career, but after 100 years you need to look at what you're doing, and what needs to be changed. We're definitely getting signals from Congress who provide our funding that changes are needed. That's what's been driving the things that I will discuss with you today.

From your perspective as investigators, the problems with how we had been

organized was we had overlapping service offerings, and differing requirements, which led to delays in review and rejected proposals, equal, and generally, a decreased ability on your part to do the research, which is what we need. The approach to this was to implement new processes that enable investigators to more efficiently navigate the VA Research application process to rapidly launch research that improves the health and the healthcare of Veterans.

What will replace the services? First of all, this is where we had been, and what raised concerns with Congress, and some of our other stakeholders. We basically had four services shown here, and then we had independent programs in the services to address different areas of Veteran needs.

You'll see Veteran need A on the left. Maybe you want to think traumatic brain injury. Biomedical have their own program for TBI, and Clinical Science had a TBI program, and Health Services, and so forth. Other areas were similar. While there were efforts to coordinate those activities across the organization, that was not a fundamental part of the organizational structure. The organizational structure was built around the research disciplines, and areas of Veteran need were secondary, and by result, fragmented in the organization.

This is the new organizational structure. In the light blue on the left, you see what we're calling actively managed portfolios. On October 1st, there will be five of those shown here: traumatic brain injury, suicide prevention, pain and opioid use, military exposures, and precision oncology.

On the right, you see what we're calling broad portfolios, and those are health systems research, rehabilitation research, development and translation, medical health, and brain behavioral mental health. The actively managed portfolios are focused on specific areas, and their job is to support research to improve the care of Veterans in their focus area.

The broad portfolios are set up to cover all the research that we're currently doing from basic research to translation within the broad areas shown on this. We're showing in the green that the, above these, we're moving to a new governance structure with an ISRM Leadership Council, which has representation from all of the portfolios and programs. A new shared governance structure, which I'll talk about a little bit later on.

The scientific review groups that you're all familiar with are not changing, but they are organized under the new broad portfolios. The actively managed portfolios do not have scientific review groups of their own. There has been some reorganization of the scientific review groups, which is shown here. Basically, of A, B, C, D, E committees, which used to be under the old clinical science service, have now moved into Medical Health.

A You'll see on the left side, a Health Services Committee and two rehab

committees have moved into the Brain, Behavioral, and Mental Health broad portfolio. Now I want to stress that not only did the committees, their scientific portfolio managers, and their purviews stay the same, but also the time that the committees meet will stay the same.

Shown in blue here are all the committees that will be meeting in the winter and summer cycles. You'll see that there's not a one to one correlation between the broad portfolio and when the committee meets. Three of the committees in BBMH will actually be meeting winter/summer cycle. Then other committees will remain on the spring/fall cycle shown here in green.

People need to understand that because in the new structure one of the primary things we're asking each investigator to do is to identify which scientific portfolio review group they want to be reviewed in. That's important because these review groups will retain their discipline orientation. In other words, if you're doing TBI, but with a Health Systems orientation, you would probably want to choose a committee in the Health Systems. If it is basic laboratory work, then it probably would be a committee in Medical Health.

Again, important for investigators to understand the purviews of the different scientific review groups, so that they can choose the one that's going to give them the best review of their proposal.

I mentioned the Leadership Council earlier. This is made up of the members listed here; so the Dep Crado [PH] for ISRM. Then we have a couple of directors under that who will be part of this, plus the directors of all the portfolios that were listed. Plus, we have programs like the Gulf War, which will have representation on this.

The function of the Leadership Council is to provide oversight for portfolio activities to promote cross portfolio communications, and then to provide a channel for ISRM to communicate to ORD leadership. Key points in this, the current services will be replaced by portfolios of Veteran need. Actively managed portfolios will provide funding to advance research in areas of Veteran need. The broad portfolios will continue to provide funding for a range of investigator initiated research from discovery to translation. They will also be the homes of the career development programs, research career scientists, and service awards.

What are the changes to the application review process? I saw a hand go by, and maybe we can take – Heidi, if you can just let, keep track of the hands? We'll try to do them at the end.

This is the cross portfolio RFAs that were posted on September 3rd. You'll see on the left side here, RFAs for Career Development Award 1 and 2, Research Career Scientists, the Pilot Research or I21 [PH], a Parent Merit

Award for research, including the clinical trial. Then a Parent Merit for research not including an interventional clinical trial; then an I50 for CORE applications; then there are corresponding pre-application RFAs, which many of you know are IO2s for each of those RFAs.

We have also now posted NOSIs, and it's Notices of Special Interest. Then let me explain what we're doing and why we did this. In the previous structure RFAs told investigators both what we were interested in, and also, how to apply for funding. We have followed the lead of the NIH, which is doing this now, and we've split that up.

The RFAs tell you how to apply and the Notices of Special Interest, or NOSIs, tell you, "What are we interested in?" a NOSI is a brief, usually a couple of pages' document that outlines a need or priority. You'll see here on the left, NOSIs based on portfolio purviews. There's one for Brain, Behavior and Mental Health, and each of the broad portfolios.

Then there's one for each of the actively managed portfolios; so military exposures, pain, and opioid use, and so forth. Then at the bottom, one of the programs Gulf War, and all of those have funding. All the portfolios in that program have funding associated with them. You want to identify a NOSI related to a portfolio with funding.

On the right side are cross cutting NOSIs. You'll see women's health and a couple of others there. It's important to realize that these are not associated with funding, necessarily. You can respond to these, but you also need to respond to one of the portfolio NOSIs as well to be sure that there's funding associated with the opportunity that you're applying to. There will be additional ones. One of the ones that's not included here that is in the process of being developed is aging, which was another cross cutting area.

Let me move on to non-clinician investigator eligibility. For career development, really no change; at least five-eighths VA employed at the time of funding, and RCS follows the current requirements. For Merit and the Pilot awards, at least five-eighths VA employed at the time of funding.

There has always been a requirement for work being done in VA or VA leased space assigned to the investigator. I presented this in a number of prior group settings, and it's caused a lot of angst. We're not trying to change the rules. This has always been a requirement. There is a waiver process that can be directed to the portfolio lead and then approved by the Leadership Council. That would be part of the pre-application process.

What's new here is for non-clinician pre-applications in the spring and fall cycles only. There's a cap of two slots for local site. With a waiver request from your station, there is a possibility of two additional slots; so one for medical health, and one for brain, and behavioral mental health.

Resubmissions of new…. I'm sorry. There's a typo here; do not continue to count against the facility cap. Once you submitted one time, you don't count against that cap. If you have to resubmit, that doesn't block other people from submitting.

The other feature here is that AMP directors can propose investigators for waivers. If you're applying to an AMP area, the AMP director obtains a waiver for that, it would not count against your facility cap. Then the other thing to be clear about is that this is only for Merits and Pilots. It does not affect CADE research career scientists or other award types.

This is the timeline for application. Again, for obtaining those additional slots, there will be an early deadline where your facility can request them. Note, that there is a different pre-application deadline for clinical trials, career development, and technology development pre-applications. For the winter cycle., that deadline is going to be October 1st, so coming right up.

But once we make the transition, then the deadline will be August 1st. Then you see the deadlines for the other review cycles. If investigators want to use MVP, they need to be – MVP data – they need to be aware that there's a deadline for them to request access to that data with the dates shown here.

For the other types of research, the pre-applications have a later due date, roughly six weeks before the application deadline. For this round, it's November 1st. The others are shown here. Then the down to the wire deadline for full applications this fall will be December 8th. Then you see the others, and then the closeout for RA is given there.

I wanted to emphasize that there are slightly different schedules. On the left here for Career Development 1 and 2 research, including a clinical trial or technology development, the key dates. The RFAs and NOSIs were posted on September 3rd. Pre-applications will be due on October 1st.

Investigators will be notified of the status of their pre-applications November 1st, and then the due date for the final application is December 8th. The summary scores and summary statements should be going out late February or into March of 2025.

For Research Career Scientist Pilot awards, Merits, not including in clinical trial, and COREs, slightly different, pre-applications are due on November 1st. Then you're notified on the 22nd about the pre-application or by then, the full application is the same due date, and again, results are released about the same time. This repeats a lot of the information that was on the previous slide. Just to skip on, so for Merit applications for research involving an interventional clinical trial, this table gives the budget caps which were taken from our current program for…. I think for many, this will not involve a change.

There may be some that will see this as a difference. At the bottom that says, "Budget cap waivers again are available for this with justification," and which go up to the Leadership Council for approval.

For Merit awards, not including an interventional trial, PIs may receive funding for up to three Merit awards. Non-clinician PIs may request three-eighths salary above the cap. There were differences in how this was handled by the services in the past. Some required the salary to be taken from the award whereas others allowed it to be added to the, above the cap. The compromise was to allow three-eighths which, sort of, parallels what goes on with clinician scientists where they get three-eighths protected time on the clinical side when they get a Merit.

Note that any additional salary requirements, so if five-eighths is needed, and so two-eighths would be required, then those two-eighths must be taken from the award. If it's a multi-PI, and the second PI requires salary, that would have to be taken from under the cap. You can only take one three-eighth salary above the cap.

The cap is 200,000 per year for up to four years. Again, there was variation in what the budget caps were across the four services. For some, this will be a reduction. For others, this is an increase. We do understand the impact for people where this is a reduction. People who are currently getting higher caps will continue to get that. We're not going to change existing funding.

We will have a grandfather period for people who are coming in for renewals in the next year or so to allow them to come in with the higher budget cap using the waiver process. Basically, there are waivers of the budget cap, so they need to be justified. They need to go through the portfolio and then up to the ISRM Leadership Council for approval.

The new processes summarized here where in the top line one and two, we have posted the RF, new RFAs, and NOSIs. Three, each RFA as I showed you, has a pre-application associated with it, and those were all posted. Your investigators will be submitting pre-applications, and they will say which NOSI they're responding to.

Again, it's important to associate the application with one of the NOSIs that's related to a portfolio or program, which has a budget. Then with acceptance of the pre-application, then full application is submitted.

The application in the second line is assigned to the appropriate scientific review group. The SRG reviews and scores. The second line is essentially no change from what we have been doing in the past.

The third line, funding, each portfolio will rank the applications that were submitted to it, and will develop a ranked list with a funding recommendation based on their available funds, which will go to the ISRM Leadership

Council. Basically, the council review the recommendations. If there are budgets that are pulled up or pushed down based on priorities or other considerations, then those will need to be justified to the Leadership Council.

Then once the final approval has been given, then the funding decision notification will go out to the investigator. Then the bottom line is the management of the project will stay with what you're used to. The scientific portfolio manager who managed review in most cases will be managing the project. But they will work with the portfolio director of the portfolio through which the application was submitted.

From the view of the investigator, basically, the investigator will pick the portfolio NOSI, RFA, and the scientific review group that they feel is appropriate for the project that they're submitting based on the purviews which are on the ORD website. They will submit a pre-application providing basic project information in the requested portfolio, and NOSI scientific review group. Upon approval, and I should mention that the pre-application review is not a scientific review.

It's a technical and administrative review. It could result, if there were concerns about the scientific review group that was requested for the portfolio, we would try to reassign it within ORD to the appropriate groups. We would let you know. Upon approval of the pre-application, you will submit a full application through the portfolio that the NOSI was linked to.

You would include your approval letter, which will indicate the NOSI that you're responding to as well as the assigned scientific review group. Then you wait, and hopefully at the end of that period, you would get your scores summary statement, and the intent to fund letter.

Takeaways for investigators: What has changed? The funding opportunities are organized by the type of research proposed. Accepted pre-applications are required. Pre-applications are submitted to the cross-portfolio, pre-application RFAs, SRGs, review for all portfolios, not just for a single portfolio. Scored proposals will be ranked in a portfolio funding meeting. Ranked applications will go to the Leadership Council. Then funded projects will be managed by the SPM who managed review. Again, those things are what you're used to. I'm sorry, those things are the things that have changed.

What have not changed, so what will be the same for you? RFAs are posted and applications are submitted through Grants dot gov and eRA Commons. ORD-wide RFAs will still support this full range of research activities. The purview of the SRGs and the timing of their meetings has not changed. The scientific portfolio managers who manage the SRGs has not changed.

Review by a specific scientific review group, we encourage you to request. Applications not funded may be resubmitted no more than two times, -A1 and -A2. Once a decision has been made about an application and the notice

of intent to fund will be sent. PIs with approved applications will be required to complete just-in-time. If funded, the SPM will manage the review of the application will manage your project.

A lot of similarities; what are the changes to the funding decision process that I alluded to? The budget for each portfolio is discern, determined by the ISRSM Leadership Council at the beginning of each fiscal year. How's that done?

The value of the projects from the end of the prior fiscal year are added to any additional, specific funding provided from the budget or elsewhere for that portfolio. That total then gives the budget for that portfolio for the year. I note that the Leadership Council does have the authority to transfer funds between portfolios during the fiscal year, if that's required, for one reason or another.

The funding process, applications for funding will be reviewed in either the standing scientific review groups. Or in some circumstances, there may be special review groups. Portfolios will hold funding ranking meeting for each review cycle in which they have applications. They will come up with a ranked list. Based on their budget, they will say which ones they recommend for funding. That will be submitted to the Leadership Council. Again, if they're deviating from scores, that needs to be justified, and then would be approved by the Leadership Council.

The review timeline, I've already talked a little bit, but to summarize. The due dates for pre-applications, full applications, reviews, margin meetings, will remain on the same cycle as we transition from the services to the portfolios. The scientific review groups that were originally Health Services Research or Rehab will stay on the summer/winter cycle. The ones that derive from BLRD and CSRD will remain on the spring/fall cycle.

What's changing? On September 3rd, we posted our new ORD-wide RFAs portfolio pre-applications and notices of special interest. The old RFAs will be coming down over the next month or two.

In conclusion, on October 1st, we'll transition from the four services to nine portfolios. Service RFAs have been replaced by cross-portfolio RFAs, and Notices of Special Interest. The scientific review groups will remain the same. Portfolio funding recommendations will go up to the Leadership Council, which will make the final approval.

I want to end back on our 100-year anniversary. We're trying to prepare ORD for the next 100 years of operation. We're adopting a new organizational structure that's focused on areas of Veteran need. We're adopting new processes which we think will enhance innovations, speed our processes, and more rapidly respond to the needs of Veterans, and other requirements.

I'll end with my e-mail because I'm sure I won't get through everything. All the questions that we have today, I am asking Heidi to capture any questions from the chat or that we don't get to before 1 o'clock. Let me… I guess I can….

Well, before I unshare, Heidi, there were some people who put their hands up as I was going through my talk. Before I stop sharing, do you want any –? Can we find out, if there's somebody who had a question where they would like to go back to the slide to ask their question? I'm happy to back up.

Heidi Schlueter: Right now, I only have one person with a hand up. I'm not sure of their full name, but they're in as…. I've got a couple of people. Now, the thing to remember you guys, if we are unmuting you so you can ask a question, you're asking the question. Then we have to remute you because we have a lot of pending questions in the Q&A. If you have a submitted a question, yeah. See, the problem now is we're getting a ton of hands. This is, we may run out of Q&A time for this. But we'll start with the first one, which is Chinmen [PH]. I sent that request to unmute.

Chinmen: Mute it. That's it. We, coming out of the last round of applications, we don't, we still don't have our decisions about funding or even comments yet. Yet, the deadlines for the next round are very soon, and we're probably not going to be knowing whether we get, we're getting funded or what our even comments are before we have to resubmit.

Is this a function of just the transition? Is it always going to be like this where we don't know what our funding determination or comments before we have to apply to the next round? Because that's kind of challenging to know whether you should reapply before you even find out.

Christopher Bever: Thank you for asking that question. Hopefully, for the people who are the November 1st deadline for pre-applications, they will have all that information from the prior round before they have to submit. This would be mainly the Career Development Research involving a clinical trial, and the technology development applications. For those, they have the deadline of October 1st for the pre-application.

My advice would be to be prepared, if you need to submit that pre-application. Maybe we can have a general, if we know which services you're waiting for results from, we can see if there's any way to get that out quickly before the pre-application deadline. I was an investigator for 29 years before I moved to Central Office.

On a number of occasions I was working on my revision, not knowing whether I was going to be funded or not; and either, I ended up in a good position of having been working, and being ready to be submit, to resubmit, or alternatively, at the last minute finding out that I had been funded, and not having to submit.

I understand the quandary that your investigators are in. Again, if we can internally, and ORD identify where we are, try to get the word out as quickly as we can, so that people are prepared for that October 1st deadline. Thank you for the question.

Heidi Schlueter: Our next question is…. But I lost it. Dan Blonigen PH], I just requested you to unmute yourself.

Christopher Bever: I'm sorry, I can't hear. You're going to have to get closer to the microphone or speak up.

Dan Blonigen: My apologies, is this better?

Christopher Bever: Yeah.

Dan Blonigen: Okay. Thank you so much for this presentation, and all the time you've taken to explain all the changes. My primary question is something in the RFA that some investigators at our Health Services Center have wondered about. That I think this may apply to all the RFAs, but it was for the non-clinical trial RFA where the instructions to that investigators could only be a PI on one application submitted to a particular RFA in any given review cycle.

Christopher Bever: Right.

Dan Blonigen: I know, in one of your slides earlier you talked about some rules or exceptions to that, I think, for maybe the medical portfolio in particular. But is that instructions in the RFA just for new applications, meaning a PI can only be, someone can only be a PI on an application for a, on a new submission on a given cycle? But if they have a resubmission, can they also submit to that particular RFA at the same cycle since it takes three cycles –?

Christopher Bever: Yeah.

Dan Blonigen: – To maybe get funded?

Christopher Bever: Great, great point, thank you for raising that. I agree, there is ambiguity there. My understanding was we were trying to limit it so that each investigator only put in one application to one RFA in a round. If you are already funded under that RFA, you should not be prevented from submitting under that RFA in a different cycle. Does that make sense or answer your question?

Heidi Schlueter: He is remuted, so he's not able to answer that.

Christopher Bever: Sorry, you're muted. Yeah. My understanding of that is that the prohibition would be only that you can't submit multiple applications in one cycle to one RFA, but you could in different cycles.

Heidi Schlueter: Great, thank you. Our next question here is Aliya Webermann. I just sent you a request to unmute right at the bottom of your screen.

Aliya Webermann: Thank you so much for the presentation. I was wondering specifically about the HSR for scientific review group within Brain, Behavior, and Mental Health. I'm a bit confused about the due dates because for the broad portfolio for Brain, Behavior, and Mental Health it says that it's a spring/fall cycle. But then for HSR 4, which I think my research will fall into, it says winter/ summer. I'm just a little more confused. If you don't mind clarifying that? Thank you.

Christopher Bever: Yeah. You follow the cadence of the committee that you want to be reviewed in.

Aliya Webermann: Okay.

Christopher Bever: I tried to point out in my slide with the green and blue colors that those two committees that are in BBMH that came from Rehab, and from HSR will be meeting out of sync with the other committees in that broad portfolio. They will continue on the winter/summer cycle that they have been meeting on for the past, I don't know how many years. You want to time your application around the scientific review group that you want your application to be reviewed in.

Aliya Webermann: Okay. Excellent. Thank you so much.

Christopher Bever: Thank you, good question.

Heidi Schlueter: Thank you. Our next questioner is Heidi Silver. Heidi, I think you lowered your hand as soon as you unmuted yourself, and that remutes you. If you still have a question, please re-raise. We're going to move to Jennifer Stevens-Lapsley.

Jennifer Stevens-Lapsley: I was wondering what the definition from the VA is of a clinical trial? For many of those CDAs, they're not proposing a full-blown clinical trial, but they're working with, they're doing pilot feasibility studies related to clinical trials or setting the stage for a clinical trial. What's the VA's definition of a clinical trial currently?

Christopher Bever: Good question. In terms of the two RFAs, it's an interventional clinical trial because the NIH has a very broad definition of clinical trial. I think to actually give a definitive answer to your question, I would have to defer to Miriam Smyth or Kristina Nord. Rather than giving you information that's not going to be correct, let's take that question, it's an important question, so let's take it offline so that we get an authoritative answer to it.

Jennifer Stevens-Lapsley:

It sounds good. Thank you.

Christopher Bever: Thank you.

Heidi Schlueter: Our next questioner here is, listed is, and here's Alexandru Moliva [PH].

Alexandru Moliva: Thank you so much for the great presentation. I just have the question regarding the number of caps. You were talking about, there's a, that each facility allowed to have two caps per cycle, two pre-application caps per cycle. Maybe I missed understand that, but could you please clarify that, please?

Christopher Bever: Yeah, thank you for the question. There has been a lot of confusion and questions around that. First of all, the cap only applies to half of the cycles. It applies to the spring and fall cycles, not to the winter/summer cycles. For the spring and the fall cycle, each facility can submit applications from two new non-clinician investigators. This doesn't affect clinician investigators at all. It's only….

It doesn't affect currently funded investigator, non-clinician investigators who are coming in for a renewal or people who had, non-clinician investigators, who have had funding within the prior, that ended within the prior year. This would be new non-clinician investigators. Each facility has a cap of one application for Medical Health and one application for BBMH, Brain, Behavioral and Mental Health.

They, each facility, is allowed to ask for an additional one or two caps with justification. Again, it's a limited number of possible applicants that are affected by this. It's basically new non-clinician investigators. It's only the spring and the fall cycles that are affected. I hope that clarifies it. But again, I know, there's a lot of confusion around that.

Heidi Schlueter: Thank you. Our next questioner is Carol. I don't have a last name.

Carol: University of Nebraska, and the VA in Omaha; and my question, I think, was answered. It's related to non-clinician scientists who currently have merits that have been funded 6/8ths, 7/8ths, or 8/8ths, and would those change during the course of the tenure of the merit? I think the answer was that, no, that that would not happen. It would be looked at in later cycles.

Christopher Bever: Basically, if somebody has more than five-eighths on their merit, and they come back in…. I mean, if they already have it, then we're not going to change that in the course of their merit. No, we would not change somebody's salary support during the course of a merit. If they come in for renewal having had that higher level support previously, probably.

We haven't decided on the exact grandfathering period, but let's say it was in the next year or the next two years, then they would put in a waiver saying,

"For these reasons I've been getting salary, this additional salary. I need to have a waiver of the cap." Then that would be considered at the Leadership Council level.

Again, we're not going to change anything that we've currently committed to, and we're going to try to provide some flexibility during the transition period over the next couple of years for people who are used to a particular level of funding, and it's been changed by this reorganization. Thank you for the question.

Carol: Thank you.

Heidi Schlueter: Our next questioner is Dawne Vogt.

Dawne Vogt: I hope you can hear me. My question –

Christopher Bever: Yeah.

Dawne Vogt: – Also pertains to the HS4 review group. I am going to be putting in a resubmission. You presented a table where you had the review groups aligned to the portfolios that have NOSIs linked to them, I believe. HS4 was linked up to that behavioral mental health one. My question is this. If I'm resubmitting, and I wanted to go back to HS4, does that mean I have to submit to the Brain, Behavioral and Mental Health NOSI, so that it will get to that review group?

Christopher Bever: No. In your pre-application you can independently specify what NOSI you want and what scientific review group you want. If you believe that your application best fits with the Health Systems Research broad portfolio, then you would specify that NOSI. Then you would specify the group, scientific review group, that you want.

Again, those are two independent things. You don't, even though the HS4 group is now administratively under Brain, Behavioral and Mental Health, and the scientific portfolio manager reports to that portfolio executive director, again, it retains the Health Services orientation. The scientific portfolio manager will be somebody with a health science background or health services background. The purpose of putting it there is not to change it, but rather to bring a Health Services orientation into BBMH. I hope that's clear.

Dawne Vogt: Thank you. Thank you. I appreciate it.

Heidi Schlueter: Thank you. Our next questioner is Aliya Webermann.

Aliya Webermann: I already, actually went, so.

Heidi Schlueter: Okay, I'm sorry.

Aliya Webermann: But I can ask a question. Actually, my colleague had her hand up, too, but she might have gotten skipped. I can ask while I'm unmuted on her behalf.

Christopher Bever: Okay.

Aliya Webermann: Which is, so she is putting in a resubmission for an HSR CDA-2. She was unclear about whether the MRA0 scientific review group within HSR would be reviewing CDA to resubmissions. It seems like she's gotten some guidance that applicants would need to identify a new SRG, and wasn't sure if that was consistent with what was shared in the presentation today. Thank you.

Christopher Bever: I would refer her to the scientific portfolio manager that she had worked with or to Liza Catucci, who's the deputy of the HSR, to the broad portfolio in October. The reason is, I think that HSR has been changing their process. I believe that they had had a separate committee for CADEs in the past, but the portfolio manager for that retired from VA.

I think that they have shifted so that now CADEs will be reviewed in their portfolio, in their scientific review groups. I'm not in HSR, so I would want them to check with HSR leadership to make sure of that, and to confirm which committee. I mean, if that's true, then they probably need to have a discussion about which committee would be the most appropriate for the CADE application that this individual is preparing. I hope that helps.

Heidi Schlueter: Thank you. Our next questioner is Lynn Huber. Lynn, you need to unmute at the bottom of your screen. It looks like she may not be available. We'll move on to Barbara Bokhour.

Barbara Bokhour: Regarding resubmissions, one is, I think, I think what Dan Blonigen was asking earlier. If I am resubmitting to, let's just say, it's a non-clinical trial RFA. I'm resubmitting an old, an application. Can I also submit a new application at the same time to that RFA?

Christopher Bever: Good question, I don't think we've considered that internally as a possibility. Rather than giving you an off-the-cuff answer to that, let me take that back.

Barbara Bokhour: Thank you. Because I do think that's a common occurrence. People have their third submission of something, but they're trying to get funded so they also put in a new application.

Christopher Bever: Okay. In that scenario, they would be submitting two applications under the same RFA. We need a clarification. We have said that you can only submit in one cycle to, one application to one RFA. But would we allow, if somebody is in this resubmission process, that they could then put in a second application to the same RFA?

I think, again, we're trying to support investigators. My inclination would be

that we would allow that. But again, let me take that back before I say that that's the final word on it, and make sure that we have agreement in our leadership.

Barbara Bokhour: Okay.

Christopher Bever: Great question, thank you. I'm sorry that we hadn't thought that carefully through all those details. But I could see where that could be very important to some investigators.

Barbara Bokhour: Can I ask one other quick question about resubmissions and budgets, which is, if you're….

Christopher Bever: Yeah.

Barbara Bokhour: If you currently, if you've had a review, you've gotten your reviews, you have put in a budget of, let's just say, $1 million. You're resubmitting for the nonclinical trial RFA. Do you now need to adhere to the new budget guidelines or can you use the old budget that's now been, from the last review?

Christopher Bever: Yeah. The broader issue of resubmissions is we have a bunch of people who submitted proposals before October first and are now, were not funded, and are now resubmitting after October first after we've made this transition.

Barbara Bokhour: Right.

Christopher Bever: The question is, you should get your A1 and A2, but how do we do that with the RA? The bottom line is that we are going to submit A1s. We are going to support A1s and A2s from those people who got their A0 in before the transition. But we're going to have to do some manual management of that in order to work it through the system. When you apply to ERA, I think ERA is going to think that your A1 is actually an A0 because it's a new RFA or so forth. There's going to have to be some manual work on our part to make that happen. But we are committed to doing that.

Some of the budget caps were higher under the old system than they are now. When you come in with your resubmission, you're going to be required to put in a pre-application, and you're going to need to state in there, or ask for a waiver, basically, "That I had submitted my A0 with this budget, and so now I need a waiver, basically, to allow me to continue with that budget." We're going to try to be supportive during this transition period.

Barbara Bokhour: Thank you very much.

Heidi Schlueter: Thank you. We do have two minutes left in the webinar. Dr. Bever does have a hard end at 1 o'clock, so we are going to respect that. We do have well over 100 pending questions in the Q&A, and a lot of people with hands up. For

those of you with hands up, please submit _____ [00:56:47].

Christopher Bever: Yeah. Can I ask that the people with their hands up, can they put their–? If they didn't already put their question in the chat to put it in the chat. Last time I went through the questions….. Heidi does some organizing for me. Thank you, Heidi. I will provide responses and then Heidi will send them out to everybody who is on the call. We'll try to deal with your questions.

I apologize for not having more time to go through questions, but I do very much appreciate the questions. Because as you've seen, there are some details in this that we have not gotten to working on. It's very helpful in illuminating areas where we need to provide further clarification. Thank you, everybody for your participation in the program today.

Again, there will be follow-up. The slides that I used will be sent out to you with an update over what went out before. Give me ten days, but we will get answers to all your questions out.

Heidi Schlueter: Fantastic.

Christopher Bever: Thank you, Heidi. Do you want to close things up?

Heidi Schlueter: Well, actually, I was just going to tell the audience, I'm going to leave the meeting open for just a few minutes. If any of you are typing questions in, so you've got a few minutes to get those in. There'll be no –

Christopher Bever: Thank you.

Heidi Schlueter: – No further presentation, but just a few minutes to get those questions in. Thank you, everyone, for joining us today. We will see you at a future session. Have a great afternoon, everyone. Thank you.

Christopher Bever: Bye-bye.

Heidi Schlueter: Okay. Thank you, everyone. It looks like the questions flowing in have stopped so I'm going to go ahead and close the meeting now. If you do have a follow-up question, please feel free to send it over to Dr. Bever. We will capture those questions for the FAQ that will be sent out for everyone. Have a great afternoon, everyone.

[END OF TAPE]