Q: Where is HSR4?

Mental & Behavioral Health

Q: Where does epilepsy research belong? I don't see that listed. How about neurogenetics research?

Epilepsy. That would still be under brain behavioral mental health in the same old panel that's been dealing with it. So that SRG hasn't changed.

But whichever panel has been dealing with neurogenetics would continue to handle that.

Q: Will Career Development Awards only be available through HSR and Rehab in the new broad portfoilos?

So all four broad portfolios will continue to have career development. So yes, rehab and HSR will have career development, but so will brain behavioral mental health and medical health.

Q: What will happen to the grants submitted last round?

So the issue is if you submitted a grant before the transition, sorry if you submitted an application and your application was not funded can you get your A1 and A2? And yes we're committed to giving you your A1 and A2. And that requires that we're going to have to be manually tracking those proposals as they come back as A1's and A2's. Because ERA is going to think that proposals are going to be new. And so potentially ERA might give you three more cracks, which obviously we can't do. So yes, people who have submitted before this, the transition will get their A1's and A2's. Thank you for the question.

Q: Can you speak to the duration of the specific AMP areas? That is, the frequency by which they will be (re)evaluated and new specific AMP areas identified?

we haven't set an exact cadence for the evaluation of each of the portfolios, but we do have a kind of template for portfolio evaluations. And we – a year ago we set up some test portfolios to kind of test out the concept. so thank you to Amy Kilborn, David Atkins and the other people in health services research who stood up new health systems research broad portfolio to allow us to test that out. And they have completed an evaluation which is just going to the ISRM leadership council this Thursday. And then the other two test portfolios where Ken Myrie was an individual and senior portfolio manager led actively managed portfolio and then the other test actively managed portfolio. And thank you to Audrey Kuziak, Kathy Plaszak, Carol Fowler and Giandi Sankar who formed a team leadership for the pain and opioid use actively managed portfolio. So we're going to be doing a formal evaluation of those test portfolios over the next couple of weeks. And use that to inform standing up the nine portfolios that I described to you. And I should say there's been ongoing evaluation, not formal but informal, as those portfolios have functioned. And we've learned a lot from them and made changes to how we're going to structure the new broad portfolios and actively managed portfolios based on that experience.

So you know, I'm thinking that we'll probably come up with a schedule where the portfolios will probably be evaluated every three to four years, something like that. Again a final decision hasn't been

made. And then in terms of new actively managed portfolios we have a process for establishing new portfolios. It general requires either congressional or White House kind of pressure to establish a new portfolio. So these are not likely to be coming up out of groups of investigators, or from that stakeholder kind of group. That's not impossible. But again the portfolios that we have now are coming out of legislative or other congressional mandates or you know from the White House like precision oncology, and the cancer moonshot.

Q: In earlier versions of this reorg presented to the Geriatrics and Gerontology Advisory Committee, the broad portfolio was entitled "Medical Health and Aging". That title appears to be gone. Where are researchers in aging supposed to submit?

Early on we made this decision or judgment that we should establish medical health and aging broad portfolio. But when we thought it, aging issues crop up in rehab, they crop up in TBI. If you look at what we currently fund and what falls into the aging area, it's like 53% of what we fund. So try – as we started trying to work through it, and think what would that mean to have a broad portfolio that included aging, are we going to move all aging into that portfolio? And I don't know, so we engaged internally. And we engaged Marianne Shaughnessy and other people on the clinical side of aging. And where we came down was to accept the fact that aging is going to be part of almost every portfolio that we've got. And that it would be better addressed with an integrated project team or research integration work group. So Holly Kroll is standing up a work group that's going – does include Marianne Shaughnessy and hopefully will include some of our clinical partners on the aging side. As a way of bridging across all our portfolios.

So basically that gives us visibility through that group into what aging research is going on in each of the portfolios. And it also gives expertise to each of the portfolios, so you think about I don't know arbitrarily picking Joe Constance, not pick on him. He probably – is probably not true of him, but every amp leader doesn't necessarily have a lot of knowledge about aging research issues. So by having suicide prevention amp, have representation on the aging research integration workgroup, then that group can provide expertise back to suicide prevention. What are the issues related to aging that need to be addressed? So we just thought it was a better way of addressing the issues of aging, which are so broadly present in our program. Than trying to put it in one portfolio. So I hope that fully answers the question.

Q: Will there be a mechanism for non-hypothesis-driven research proposals, such as studies to optimize/standardize immunosuppression regimens for cell transplantation.

So I'm trying to think where that fits. I guess it might fit under pilot projects, or it may fit under tech transfer. But I think at various times we've had offerings for non-hypothesis driven developmental work. In fact, I had an aware from rehab at one point for some development of robotic rehab devices. So I know we've done that in the past. There is nothing currently in the listing that I showed you and addresses that. But you know maybe we need discussions with Brian and others in ORD about whether there's a need for something specifically focused on the development of devices, and even pharmaceuticals or whatever.

And Arun Sharma has been leading the group on technology development. And I would defer to him on whether what you're specifically asking about would fit under the RFA that he has put together. So thank you for the question, and I think that's something that we need to follow up on.

Q: Are there going to be changes to budget caps to make is easier for an application to be transfered between services?

So that was one of the purposes. We've had this situation in the past. I mean I had it as the director of BLRD. Rehab would have a great proposal that they decided was out of their purview because it was hypothesis driven, mechanistic research. And it would be sent over to BLRD and because a their cap was different we couldn't accept the application as it was submitted. So we hope that by adopting a standard cap across the organization we will get rid of that problem, so thank you for the question.

Q: What will happen to applications submitted to existing RFAs this Septermber, if they need to be revised? Will they be under the old RFAs and requirements, or will these change for the March resubmission?

So if you look at the new cross portfolio RFA's they're pretty broad. They've been authored by representatives from all the services. So they are supposed to encompass all the aspects of the different service specific RFA's that we have now. And so I would hope if you look at the new cross portfolio RFA, you would find that your prior proposal would fit with that. If not, you need to reach out to your scientific portfolio manager. But I would know one thing, and that is you know if your budget doesn't fit with the new budget requirements then either you're going to have to change it to fit the budget, or you're going to have to have a waiver to allow whatever the budget is. So thank you for the question.

Q: Could you please clarify which portfolio CSR&D falls under? Thank you!

So basically CSRD as a service is going away. Some of the scientific review groups that were under CSRD will be going to the new medical health broad portfolio. So to oncology panels that were under CSRD will be under medical health. and then the mental health panels from CSRD will end up in the new rain behavioral mental health broad portfolio. I think that covers them all, thank you. And while Pauline is looking, just let me comment that I'm doing the best I can to answer the questions. And if I don't fully answer the question that you raised, if I misinterpreted what you wanted or didn't give everything, my email is shown in the slide right here. I would welcome having you send me an email saying, "Chris actually what I was asking was XYZ, can you help me with that?" If I don't know the answer, I will take it on to someone else in the office who can help me put together the answer. And so if I say in this that I didn't know the answer, couldn't answer fully, a follow up email wouldn't hurt to remind me that I need to reach out to somebody in the office.

Q: How will the NOSI be publicized? Is there a listserve for investigators to subscribe or will they appear on the research websites similar to current general PAs?

Our plan is I think all of you know, or many of you know that currently when you go onto the internet site there is a web page that has table, a big table that lists all the RFA's. And the idea is that we will establish either an extension of that page or a new page that will have two additional tables. And one of the tables will be the new RFA's, and the other table will contain all the no see's, or I should say these are the titles of links to the actual documents. So we're going to follow the current process and once we are done with the old RFA's then that page or table will be sunset, and the new one will be all that will be left. And while they're both up there we'll try to have very prominent disclaimers saying that this table will be in effect until the end of September. And then this other table will take effect for applications submitted after October 1. So if people – so that's the current plan. If there are additional things that we should be doing,

that we're not thinking about please send me a note, an email. My email address is right here on the slide. Making that suggestion. We're certainly – we want everybody to have access to these things. And so whatever we can do to publicize them widely, we would want to do. Thank you.____

Q: How will the changes affect the VA-MERIT clinical trial PA?

So I think I tried to point out earlier that we're going to have a cross portfolio of research, including the clinical trial. So clinical trial applications would come in through the no see of the portfolio that we're responding to. So if you're doing a TBI clinical trial, you would come in through the TBI no see. If you're doing a clinical trial that didn't fit in one of the actively managed portfolios, then you would figure out which broad portfolio it was most appropriate for, and you would come in through that no see. And the clinical trial RFA. Again we want to see the pre-applications for those early enough for us to give feedback to you, which has been the practice since CSRD in the past. But not in HSR in rehab, so a little bit of a change there. We try to give some early feedback on clinical trials to help people come in with better applications.

Then the overall review process is pretty much the same as what you're used to. It goes to committee, it's reviewed. In the study sections usually the – either the portfolio manager divides up different types of applications and deals with them as a group or you know, prominently announces that we're shifting gears here. We're going from a one kind of application to another. So I think depending on where you are, where you apply currently you may or may not see changes in the process. If you're currently applying to CS probably not too much change. If you're applying to rehab or HSR you may see some changes in terms of the pre-application.

Q: Just wondering how the pre-application is going to differ from the Intent to Submit or will these be combined?

Yeah, so the intent to submit that HSR has been using will go away. And so the pre-application is a fairly generic product in ERA. And you can, based on the requirements that you put in your RFA for it, you can have it be absolutely minimal, just an ITS. Or you can have it be very extensive, including a lot of detail about the proposal that would support significant level of review. So there may be some variations across the different offerings. But we're trying again to standardize to sort of get a core information. Less, I mentioned that there's a shorter turnaround on things other than clinical trials for development and tech transfer. So those three, there's a longer lead time and they'll be more information requested in the pre-application. The ones that are coming in later, there's less time to do anything. And so there will be less information requested. So the ITS that HSR has used will be going away and it will be replaced by the pre-application.

Q: Is there a template for the pre-application (LOI) available now?

It will be available soon. I don't think it's available yet. That will go out to the field as soon as it's finished and approved.

Q: Why is it important to separate clinical trial versus not? I realize that's what NIH does; fundamentally though, what substantive benefit does it provide?

So I think the basic rationale is risk to patients – to veterans, and risk to the agency. Research involving a clinical trial is regarded as higher risk. And so we – the NIH started doing this before we did. And we agree with the NIH rationale for making that separation. And so we've done that. Thank you for the question.

Q: How is the ORD budget distributed by actively managed portfolios vs. the broad portfolios? Are more funding allocations committed to the active vs. the broad, for example?

So I tried to describe to you how budgets were set. Basically we've been going through a process in ORD over the past few months of developing the purview for each of the portfolios. And then going through each of – going through the project list in ERA or system for managing your projects. And deciding which projects belong in each portfolio. So in other words we have decided that a certain group of portfolios, projects belong in the TBI portfolio. Another group of projects belong in the suicide prevention portfolio. Another group belong in the health systems research broad portfolio and so forth. And as you can imagine there have been some areas of overlap and there have been some contentious discussions about where things belong. But I'm please to be able to say that people have been able to work through that and come to agreements that everybody is – can live with.

So going into the FY'25 year each portfolio has a list of projects. And so you can take the dollar value of those projects and add it up. And then that becomes the base budget for each of the portfolios. And then in some cases OMB or Congress or somebody else may direct money to a specific area. And then that would be added onto the budget. Unfortunately we're in a budget contraction this year. We haven't gotten a final budget for FY'25. but if you look at the Inflation Reduction Act, federal agencies are probably looking about a 7% or something across the board cut. So where there's a cut, that has to be divided up proportionally across the portfolios unfortunately. So that's the approach to the budget for each of the portfolios.

Q: will these organizational changes encompass or effect the deployment of AI within these reasearch spheres? if so how?

So AI has – so the AI office used to be an ORD. And had been for – since just before the pandemic. So maybe six or seven years. And recently the VA has stood up a new office to manage AI, which is not in ORD. So a lot of AI is moving over to that office. We have AI pretty much across the program and meaning that many investigators are employing AI techniques in the research projects that we're funding. So for example, we have people using AI to use imaging from you know GI imaging to identify cancerous lesions. We fund research related to images from vision and other – there are many different applications as everybody is aware. And there's a lot of interest in using it. So there's AI scattered across the program. There's one focus area under health systems research. There are in the data science portfolio there are AI specific projects really more focused on AI techniques and less on specific applications. So I think to the extent that we have AI specific research focus, that is where the research is focused on AI, not on specific applications to veterans. That's most likely going to be in the health systems data science area. But not exclusively, again there is AI going on pretty much across the whole program

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Q: Are or will there be NOSI for environment on health outcomes?

A NOSI for environmental health outcomes? So yes. The military exposure research amp has a no see. And so that includes military environmental exposures, because if the questioner is asking about broader environmental exposures not specifically related to military service, I guess if that's – if they want to submit something and feel that it's veteran centric, then I guess I'd talk to Rudy Johnson for starters. And find out if he has any suggestions on where that should be best submitted. So thank you for the question. I apologize if I haven't fully addressed it.

Q: Could you clarify the statement about 1 application to BLRD being allowed from each site with a waiver for the 2nd (slide 18)

So this is a practice for BLRD that was started a cycle or two ago. Where for new – so this is only applied to new non-clinician investigators. And for that group there's a restriction of one application per site in each cycle, unless they've obtained a waiver or a second application. And again, that's been going on and the big different is that it applied only to applications coming into BLRD. It did not apply to CSRD. And now it's going to apply to basically all the committees that derived from BLRD and CSRD. So the cycles what is that spring and fall? Those cycles yeah, so that will apply to the spring and fall cycles that each site will be limited to one new non-clinician investigator. Unless they have a waiver for a second. so thank you.

Q: what proportion of VA Merits are held by non-clinicians? It seems that only allowing 1 non-clinician application per site will have a large impact

So the area that I'm most familiar with is BLRD. And what's been happening in BLRD is that the percentage of clinical investigators has been dropping. I think it became less than 50% about eight or so years ago. And as continued to drop and I just can't tell you what it is for the other services. But you know it's not the only factor to consider here. But when the research program was established in VA, one of the primary goals of the program was to be a recruitment incentive for clinicians to come to take care of veterans. And there's still a requirement if you're a clinician with VA funding that you spend 25% of your time taking care of veterans. So I worked with non-clinician investigators as a VA investigator. And they play a critical role in our programs, so I'm not trying to diminish that. But I guess what happened with BLRD about over a year ago was they abolished the eligibility requirement and they had an additional 100 and some applications as a result of an increased number of non-clinician investigators applying with some local stations submitting as many as 15 applicants. So there's a huge pool of non-clinician scientists at the affiliated medical schools, that have not had a connection to VA. Who would like to be able to apply and obviously we're not staffed to handle a 30% increase in the number of applications. And you know there needs to be discussion within ORD, whether that should be a goal. There certainly would be some advantages to bring in more non-clinician scientists. But again, it's just a matter of priorities and we have to work our way through it. So it's an important issue and thank you for the question.

Q: There has been differences in how BL/CSRD vs RRD have dealt with non-clinician salaries specifically for GRECC investigators. Will GRECC investigators (non-clinician) salary be eligible to be paid by ORD awards moving forward?

So we haven't had any discussion of that yet. So I can't tell you what the decision is going to be. To help me get on the radar screen for us to come – figure out what we're going to do. If you can send me an email or Marianne Shaughnessy, she's on our aging work group. If she can raise it, we just need to address that issue as we've gotten up to being considered. Thank you for raising the issue.

Q: Will you be adopting the NIH definition of clinical trials? Or some other criterion?

So that issue has come up before. And I think the concern was that the NIH definition is really broader than the definition that we – the VA has been using. So I think the inclination in the clinical trials work group that's working on this was to stick with the current definition that we have been using. I guess I should check back with them and make sure that is what they intend. So thank you for the question.

Q: Technology Development Awards have not been a 'standard' PA posted on the VA website in the past. Will these be in the form of NOSIs going forward or will they be assigned a separate category similar to clinical trials, CDAs, etc..?

Yeah, it's a separate RFA. So it will be separate from the other offerings.

Q: For career development awards due on 12/15 this year, does that mean the pre-application will be due ~9/15?

I haven't gone through the calculation, but if that's three months before, that's about when they would be due.

Q: Can you submit the Pre-application for Research Applications more than 6 weeks ahead of the deadline to get earlier feedback/approval?

Good question. I would check, I guess there are two issues. One is when does it open in ERA? And I think it opens before the six-week deadline. So yes, I'm pretty sure that you can submit it ahead of that. And now that I think about it, Kristy Bentengrover in Rehab called me – Rehab has been using the pre-application for a couple of cycles. And they start reviewing the LOI's as soon as they start coming in. So they don't wait until the deadline. So yes, I think you can submit it early and you can get early feedback. If I did that I probably would reach out to the SBM that I was interested in, so that they knew that it was coming in and we'd go find it.

Q: Will the pre-application only be required for ithe intial submission of the application or for all submissions including resubmissions?

There was discussion of that internally. And we came down on, we want a pre-application for every application, whether it be first, re-submission or renewal.

Q: If there was a concern/disapproval with the pre-app, will it then be allowed to resubmit a corrected pre-app for the same period?

No, you have to wait for the next cycle.

Q: Do you know the time frame between the pre-app submission and full appllication deadline? For example in the case of LOI for CDA, sometimes we did not know if they were accepted until 2 weeks prior to the submission date

So I think we had an eight- and 12-week deadlines prior to the opening. And I think in general ERA opens three or four weeks before the closing dates. So that makes 12 weeks becomes 15 or 16 weeks. And the eight weeks becomes 11 or 12 weeks, something like that.

Q: How long will it take from pre-application to receiving approval? Should we assume that most pre-applications will be approved?

So I think currently most pre-applications are approved. Investigators need time to put their application together. So we'd like to turn around pre-applications on the longer deadline within the four weeks, I would say four to six weeks of the closing of pre-applications. And on the eight weeks, within four weeks of having received them. So we haven't put down a written schedule yet. But I think it's going to look something like that.

Q: Can PIs have more than one actively funded project at the same time?

So we haven't decided on an absolute limit to the number of awards that a PI can have. I think we probably will eventually come down maybe around three, or merits, something like that. There are differences currently in how the services deal with that. And so we're having to come up with a common approach. We will have a cap of one application per RFA per cycle. And probably a cap of two applications totally in each cycle. So you would be able to apply for one merit and one pilot, but not one merit and two pilots, or two merits, whatever.

Q: Very glad to see consideration of budget challenges for non-clinician PIs. Are the new budget limits and rules available for review? Would this apply retroactively to grants currently under consideration?

So if your grant is already funded, they wouldn't apply to your award. And I guess the question is if you were picked for funding already, and your in jet, again the old budget caps would apply to that. As I said earlier if you were not chosen for funding and you were resubmitting, then you will have to comply with a new budget caps.

Q: what is the process of resubmitting an IIR application that may not get funded at thie current funding cycle (prior to impementation of these changes)

Well it will be through ERA, but it will be through the new RFA's. I think we talked about this earlier.

Q: Will "pay line" be based on the impact scores-based percentiles or rank order within each portfolio? Meaning is it going to be all top 5%-ile projects get funded? Or will it be all top 10 or so ranked projects get funded?

So currently rehab and HSRD work with the absolute scores, not the percentiles whereas BLRD and CSRD use the percentile scores. And so what we've tabletop modeled is bringing together the absolute scores for HSRD and rehab. And the percentile scores for BLRD and CSRD. And so the ranking will be based on those scores. And so it will be done differently spring/fall versus summer/winter. And there was another part to that.

Q: "all work performed in va labs or leased space "- what about sent out assays eg genomic /proteomic panels

Well I assume that the samples are being collected in VA, that most of the research prior to sending samples out for analysis is being done in VA. I think you know if there's a good rationale for sending things out for analysis that – that's been done widely and we'll continue to support that. Thank you.

Q: How does this change affect center grants?

So right now the centers they in the broad portfolios, and there's really no change to the centers. I guess the one area that could change is as we're dealing with budget constraints. There could be budget reductions in currently funded projects, we're not currently discussing doing that. But it is a possible option. I think NIH has done that in some of that areas. So that could potentially impact centers, but I think otherwise I'm not aware of any changes to the centers.

Q: Any info on plans for the old shared equipment grant program?

That's a sad story. In the past when budget was growing, we always had money. And we had sheep and lamb to fund new equipment needs in the field. Now that we're in a shrinking budget environment, we really don't have the money for that. We're kind of funding the animal needs that are crisis level. But other than that, well there's one exception I guess. The military exposure program got a big infusion of money. Rudy Johnson is the senior portfolio manager managing that, and he is working with Alex Chu on an equipment sheep solicitation. So there's one little bright spot, but otherwise it looks pretty gloomy right now.

Q: Can you speak on how applications submitted during the current round will need to be adapted for the following application season with the new requirements?

We have tried to make the cross portfolio broad enough so that whatever you submitted scientifically in the initial submission wouldn't require revision when you came back under the broad cross portfolio RFA. The areas where you will have to abide by the administer requirements like budget caps. So it will

require adjustment there or requesting a waiver.

Q: For RRD, it says will remain summer/winter, however it says that HSRD & RRD RFAs will be taken down in August '24. So will there be a winter round for RRD?

Yeah as far as I know. They canceled their spire round and spires will move into the – their regular cycle and be handled into MITI. They've been handling them off cycle by editorial review. That won't continue after October 1. But as far as I know they're moving ahead with their winter round.

Q: Will there be a VA website where the new pre-application due dates and pre-application instructions/templates are posted?

Yeah, I talked about earlier modifying those tables so that they RFA's are all available in the VA internet.

Q: will there be SPIRE mechanisms?

As I just said we're – that program is being discontinued and merged into the standard review process.

Q: Proposals are not written overnight, We are rapidly approaching timepoints where we need to know whether to budget effort for upcoming submissions. We have been hearing about new RFAs for 3 months, when will we see them?

We intend to have them up by the end of the month.

Q: What about Oral Health Research? Where it falls?

I'm not sure where oral health research falls currently. Wherever it currently is being handled, I don't think that would change. And in terms of broad portfolios, probably the best fit would be medical health. I don't know the rehab has some oral health related research. But probably medical health.

Q: Can you give an example of when you would apply to a Broad Portfolio (e.g., NURP [Pain]; RRD2) versus an AMP (e.g., Pain/OUD)? How do they interact/affect each other, if at all?

Sure. So basically if you're proposing research on traumatic brain injury there's an amp for that. So I would be applying to the amp. If you're applying for research on diabetes there's not an amp for that. So I would apply to medical health. Thank you.

Q: Is 5/8 requirement needed for all investigators or only PI

Oh great question, that's not changing. It's required for the PI, but not for other investigators on the proposal.

Q: Will we still submit ITS in HSR&D ART or will the pre-applications that the place of those

The pre-applications take the place of it and will be an ERA.

Q: BLR&D currently funds PI effort separately from direct costs. Will this policy be reflected in new RFAs?

So the compromise across the services was to fund three eighths of a non-clinician investigator salary on top of the budget cap. So if more – if the investigator requires more than an additional two-eights would have to be taken out of the budget cap. And if it's a multi-PI situation then the second PI if they require, salary would have to be taken out under the budget cap.

Q: How difficult will it be to get an offsite waiver for research in this new plan compared to current situation?

Well the current climate of contracting budget, things that can be done onsite will get priority over things that require offsite. But there will obviously be exceptions you know, if you're doing TBI research that can only be done off site. And that's in a priority area. And would likely depending, be granted a waiver.

Q: Will the 3/8 committment of salary for non-clinician scientists take effect October 1 with current active grants? Also, there was discussion if a non-clinician contributes to a committee that they may qualify for a additional 1/8.

So people have current grants will continue under the current system. This will only apply to new applications and new awards.

Q: Is there any change for CLINICIAN PI support on Merit Awards, ie there is 8's effort but no line item for SNF (Skilled Nursing Facility) cost in the budget?

No. There has been no discussion of changing this.

Q: Would HSR clinical trials which test different programs or different implementation strategies be considered a 'clinical trial' for the purpose of the pre-application?

I'm pretty sure that the clinical trial RFA that we put together. The cross – would include those. But Amy Kilborne, who was involved in that process could probably – and is now the director of HSR, could probably give you a more definitive answer on that. I'm pretty sure yes. But I would defer to her.

Q: Medical health has a section for infectious diseases. How broadly is that focused? Is it mostly laboratory oriented?

So in the past that committee approved both laboratory animal and clinical studies and clinical trials. So I don't think there will be any change in the purview of that committee. So it would cover everything from basic research up to clinical trials.

Q: Will QUERI all use the Pre-app process?

We do not anticipate QUERI using the pre-application process for this next cycle (Winter 2024 cycle).

Q: Will the RFAs that targeted researchers who are veterans still exist? Also with the new push for support of spouses and family members of veterans who work at the VA, will there be in NOSI or some type of support for those that fit within that umbrella.

As you saw in the listing at this point, we don't have a no see stood up for that. but that is important priority for us. So once we get the basic one's up there's a group of additional ones we need to work on, and that should be included. So thank you for bringing that up.

Q: How is funding decision making handled by the ISRM council? Is there a charter that spells the roles, responsibilities, processes out?

So there is a charter for the ISRM leadership council. It doesn't get to the level of detail to go through all that. So we're going to have to develop written policies and procedures that set that out.

Q: Do all applications now require that the PI has current eligibility?

So I think they're looking at current RFA's. The current RFA's are the current RFA's. They're all basically working under the current rules, whatever applies. so the things that I've described to you will only change after October 1. We are going to be posting things later this month. So that people who are applying after October 1 have those and can get started on them. Eligibility, nothing is going to change until after October 1. So whatever the current rules are, are the current rules. And you have to follow them.

Q: if the ISRM won't transition from the four services to the nine portfolios until 10/1 but the CDA preapplications are due 12 weeks before the due date how am I supposed to submit a preapplication in time for the winter cycle?

So I'll have to go back and look. I thought that there was time in there for that. My apologies if that's – if there's not time.

Q: Will the VA launch the CDA-0 for graduate student support?

We don't have one now because of issues preventing us from supporting graduate students basically. So I'm not aware that there's been any change that would allow us to do that. But I guess if somebody knows of some change, they would email me what the change has been. I'd be interested to know that.

Q: How will COINs be handled under this new model?

The COINs, like centers. stay with the broad portfolio. And as far as I know Amy is not contemplating any particular change.

Q: For CDAs, if a mentor is a co-I on a merit, does this fulfill the past year merit award requirement? Also, is it 12 months from the full application or 12 months from the preapp?

If your co-PI on a merit can you be a mentor on a cade. And I would have to defer – there's not going to be any change in that as we shift to the new organization. So whatever the rules are currently, would apply going forward. I don't know whether that helps. I just don't remember what the specifics are related to that currently.

Q: how about the newly BLRD merit grant awardee that want to apply for Career scientist award?

There will continue to be a career scientist program. I guess you'd have to decide whether you fit better under medical health or brain behavioral and mental health. And apply to the appropriate – to the appropriate program.

Q: Should we somehow flag A1s that are going in for the Fall Cycle?

I guess it wouldn't hurt when you're putting in your pre-application to mention it had been reviewed. And that this is an A1. Hopefully we'll be able to recognize that RN, but that would be a fail safe to make sure we don't miss that.

Q: Given overlaps between Medical Health and Health Services, who will determine which area a grant will be sumbitted?

Well I think for starters the investigator says where they want their proposal to be funded from, so they would be applying either through the no see, or health services or medical health. And then when it gets into the system there can be discussion. And again if there was a feeling amongst the involved people in ORD that it really should have been in the other portfolio, it could be moved over. And hopefully with the uniform structure that could be time without requiring you know major revision. But moving from health services to medical health would involve a three-month delay because those committees meet three months out of phase with one another. So if it were going to rehab, from health services that could be done in the same cycle. But if it's moving to either BVMH or medical health and there would be a delay.

Q: would we still to send a letter of intent in advance for A2 and A3s?

Yes. A1 and A2's. There's no A3 as far as I know. A1's and 2's will require pre-application.

Q: Will proposals submitted during the last cycle be eligible for the non-clinician 3/8ths addition to the budget cap?

So I'm not exactly sure where this – so this application was submitted last cycle. And if it was approved it just goes forward with whatever the structure was at that time. We wouldn't retrospectively apply the three-eights above the cap to that award. If it came back for resubmission then the budget would have to be revised and then yeah, at that point the three-eight's could be added on for the A1 and A2.

Q: Can you share any recommendations for a competitive 5/8th waiver?

Competitive 5/8's waiver. Yeah you're working in a priority area would be one reason, occasionally we grant them because people have got another – like a major NIH grant of some sort. And they can't take the 5/8's. I would say we have been very strict about that 5/8's requirement. So there's a high bar to get the waiver.

Q: would pre transition application need a pre application submission for A1 and A2

Yes the pre-application will be required for A1 and A2.

Q: Should upcoming submisons, including initials, A1 and A2, take into account non-clin PI budget change (3/8 salary above cap)? For September submissions?

So an application that comes in before October 1 is submitted and reviewed under the currently existing rules. And applications that come after October 1 will – the new rules will apply. So in terms of 3/8's above the cap, if it came in before October 1 again, you couldn't ask for the 3/8's above the cap. After that you can.

Q: Could you explain what is meant by the Career Development programs RRD8/9 that are listed in the Rehabilitation column on the broad portfolio slide?

No I can't. I mean we can take that offline and try again to insert it or you can just reach out to rehab and ask them. Those are the committees that are currently listed by rehab. So I don't know._

Q: Up to now, Rehabilitation targets functional outcomes and CSR&D target symptoms-will this distinction be maintained?

So all of the services have projects that address functional outcomes, but not all of them do. In the current system rehab limits itself to proposals that consider functional outcomes. So I think going forward rehab will continue to focus on applications that include functional outcomes. But you know, TBI, other portfolios will also continue to include projects with functional outcomes. So I think functional outcomes will not particularly help you on where to put the research or where to submit.

Q: Will "pay line" be based on the impact scores-based percentiles or rank order within each portfolio? Meaning is it going to be all top 5%-ile projects get funded across portfolios? Or will it be all top 10 or so ranked projects get funded across portfolios? Or wiill decisions be based on each portfolio's budget available for new projects?

So I talk about the payline in reality what's going to happen is that each of the portfolios will come to the ISR and leadership council. They're going to say based on our financial projections we have X number of dollars to fund new projects. And this is our ranking. We want to fund the first – with that amount of money we can afford to fund the first 10 projects. And you know if any were pulled up or pushed down, then they would explain why they were pushed up or pulled down. And then the ISRM leadership council would provide approval to that. So it's not exactly like the payline established at the NIH where the NIH says the council says for this round it's going to be the 7% percentile or whatever is the payline. It's going to have a little more flexibility than that because the portfolios are going to have different amounts of money available. And the ISRM leadership councils job would be if one portfolio comes in and says they want to fund, for example up to the 50th percentile. And one of the other portfolios is funding at the 6th percentile then maybe some adjustment needs to be made there. Anyway, so that's a little more detail about the thinking on the payline, and how the ISRM leadership council would be dealing with that. Thank you.

Q: Can you please clarify how "non-clinicians" are defined? Does this include psychologists who are full-time researchers?

Basically clinicians are salaried through a clinical service in VA and provide care – clinical care to veterans through the clinical services.

Q: NIH has external advisors to each institute, I.e. councils. Does VA have a plan for such in this new structure?

So currently each of the portfolios is going to develop an advisory committee, executive steering committee. And that committee will have people outside of ORD on it. In some cases it includes senior investigators. So at this point the external advising would be coming in at the level of the individual portfolios and their executive committees.

Q: Which Scientific Review Groups will evaluate submissions to the various AMP NOCIs?

Well so again, investigators are going to be looking at the review group purviews, and deciding which best fit their applications. So if you pick for example TBI, it might be that one investigator doing a laboratory animal model of TBI would want their application to go to the review group that's managed by Amanda Hunt. That came from BLRD and after the changeover will be in brain behavioral mental health. But other applications you know might have more of a health services or rehab focus. And they would choose the committee that fit the kind of research that they were proposing.

Q: Will applications for GS14 and GS15 still be reviewed by panels or across ORD

So I think we have a promotions panel that Carol Fowler manages that will be continuing to do that. That is maybe the best would be to reach out to carol to get clarification on how that will be done going forward.

Q: Do I understand that pre application will serve as triaging area. If selected there is much better chance for success than earlier application submissions

I'm not sure that I fully under the – hopefully each pre-application will contain a request for a review committee which makes sense for the proposal, both to the investigator and also to the SPM's and portfolio directors who are looking at it. And so we'll just agree that whatever committee has been requested will do the review. But that again, if it's decided that that's not reasonable within ORD, then we can triage it to a different review panel, so that's hopefully – not sure I fully understood the question there. But I hope that answers it. How are we doing on the list? I see we're up to 157. So we're kind of coming to the end of –

Q: Is the new "pilot cross-portfolio RFA" geared towards applications for pilot clinical studies (such as pilot clinical trials) or more broadly covering clinical, translational, and basic science study applications?

I'm not sure that – I'm pretty sure that the clinical trials working group wants clinical trials all in the research including a clinical trial. So if you're considering a clinical pilot it would end up there. But I'm not absolutely sure about that. I haven't see the RFA. So we made need to follow up to give you a full answer on that question.

Q: When will specific details about the updated budget caps and what is due for pre vs final application be available?

Yeah the budget caps haven't been published yet, basically they will be in the RFA's, and we'll be sending out a notification to the fields stations. Again all of this by the end of this month.

Q: Will we still submit the ITS to HSR&D ART or will the pre-application take the place of that step

A: HSR ITS will not be submitted in ART-

Q: Will the eRA application # change, currently BX, CX, HX, RX?

The BXCXRX and so forth institute codes will continue on Legacy projects, but all new projects will come under the research and development RD institute code. We've had the RD code for a long time. It hasn't really been used for much of anything. So all of the proposals will be under one – all the projects will be under one institute code. And for the local stations point of view that makes their financial management easier. So that was one of the drivers for making that change. Because right now if they want to move money from one service area to a different service area, they have to do it as a fund transfer, which is just administratively annoying. And this makes it easier to manage their money.

Q: Will the non-clinician eligibilty pre-app be needed for all portfollios or only for the ones that are most heavily based on past BL and CS SRGs?

So they will be required for the spring and fall rounds. So any committee that is meeting spring and fall requires that the eligibility be established. And did they refer to eligibility pre-application? BLRD had used an eligibility pre-application before. And there is an eligibility requirement, but the eligibility pre-application will be dropped. There will be a general pre-application that will be required. It will be reviewed and some aspect of eligibility will be looked at in that review of the pre-application. There will not be a separate eligibility pore-application from the overall pre-application for those rounds. I just wanted to clarify that.

Q: would CDA non-clinicians be considered new or require a waiver?

So if you have a CDA and you're coming in for a merit, none of these prohibitions or caps apply to you. So if you clicked on a CDA with VA, even if you're a non-clinician, new non-clinician scientist you can apply for a merit. And you don't count towards the cap at your local station.

Q: could you explain rationale for limiting to only one (instead of five) new non-clinician investigators per site?

Yeah we just can't handle the work.

Q: Will the Biographical Sketches (Biosketches) and Current and Other Pending Support be standardized with NIH requirements? There is word we may be moving to SciENcv to produce most of the Biosketch info required - would like to know if we will harmonize with NIH and universities.

Well let me just say we're in the process of following the NIH with a new biographical sketch, which is going to be done through some sort of a contract agency. Basically all the intellectual property counterintelligence kind of concerns that are coming out of other parts of government are driving us into a new standardized biographical sketch. And there's a company – I don't remember the name who has developed this for the NIH. And VA will be following NIH and doing that. Exactly when it will be implemented I'm not clear. It probably will not be implemented by October 1 when we're making our change. So applications received you know, will continue to use the old forms. But that may change either towards the end of the year early in 2025.

Q: Can you clarify the pre-application role and processes of feedback and approval? Are there instances where Pre-applications would not be approved?

So if I – one situation where a pre-application could not be approved would be that on review of the subject matter was felt not to have significant veteran significance. That it's not, so if somebody comes in with a pediatric study, that could be disapproved. But I'm not sure whether that's any help. Eventually it's going to come down to the portfolio director working with this portfolio manager and making a decision. But I would say the rate on pre-applications generally being rejected now is low, except for non-clinician

scientists, new non-clinician scientists.

Q: How will the new budget caps work for resubmissions of QUERI projects which have a matching funds requirement?

QUERI funding announcements will be posted separately from the ORD-wide RFAs, and budget caps will be defined in the QUERI RFAs.

Q: Will the new allowance for non-clinician PIs to ask for salary above the budget cap also apply to PIs on hybrid appointments (e.g., PhD clinical psychologists with a hybrid clinical/research appointment who have to fund their research 8ths from research project funds)?

The allowance for non-clinician PIs to ask for 3/8 salary above the budget cap will apply to PIs on hybrid appointments who are eligible to apply for salary on a merit award.

Q: Since only one new non-clinician investigator is allowed per institution, how will decisions who is allowed to apply be made? What criteria will be used?

That's up to the local station. I think we will be providing some general guidelines. But many stations have that decision made in their R&D committee, but not all.

Q: Should fall cycle initial submissions follow the new budget proposal (PI 3/8 salary above budget cap)? Should we, anticipating resubmisisons?

So fall submissions are BLRD and CSRD. So if the application is coming in before October – I'm sorry, if the application is coming in after October 1, then the new rules would apply. If the application is coming in before October 1 then the old rules apply.

Q: Special programs such as the National Center for PTSD are staffed by full-time researchers. Are they no longer able to apply for VA grants.?

So I think there was a version of that question earlier. I believe they're currently able to submit awards. And if I'm wrong my apologies. So that wouldn't change. I think the earlier question had to do with can you ask for salary if you're on a center like that? So if you're already funded by a _____ 02:04:47 or the National Center for PTSD can you ask for salary? And I think we have not lowed that in the past. And I guess there needs to be some discussion of that. But I think probably that would not change.

Q: Will partial and full off site waviers request be discontinue if so this will effect sites who may not have e.g. BSL-2 labs

So I think we've been pretty liberal with partial off-site waivers. So you know if most of your research takes place in the VA, but you need a special BSL3 facility or something that's not available but is across

the street at your affiliate, then generally those partial offsites have been granted. Full off site is a different issues. We are an intramural program. And as I said before unless somehow it's a very high priority, probably we're not going to be supporting that in a constrained budget environment when we don't have enough money to fund the research that can be done on station.

Q: What are the requirements of the pre-application?

I'm not sure that I understand – so they'll be an RFA that you'll go to that basically is the pre-application for whatever the RFA is that you would want to apply to. And it will have a set of requirements. They'll be a cover page with some basic information. And then some additional pages depending on what you're planning to do. It will ask for additional information. So it's similar to letter of intent. It's just something that's embedded in ERA and part of that system. So I hope that answers the question.

Q: What portfo;lio will the Mental and Behavioral Health SMRB Panel currently within HSR fall under?

So Bob O'Brien currently has a panel on mental health related issues. It will be moving to be part of the brain behavioral mental health broad portfolio. But it will continue to retain its health services focus. The purpose is not to change it to something else or something like the other committees that we already have. We need health services research related to brain behavioral and mental health. And so that's where it will be

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Q: How will NOSIs be decided? Can program offices provide input and recommendations?

So they do. So like I mentioned before that we have a women's health no see. And the working group that put that together included representation from the clinical relevant – clinical program office partners. And so they had input into that no see. So absolutely yes. It needs to be done in a structured way where they're a part of the working group that is addressing that area. But definitely yes.

Q: If we have a non-clinician from our station who submits a pre-application and it gets approved for the full application, but that full application is not selected for funding. You said all resubmissions require a new pre-application; therefore would that one non-clinician pre-app for his resub be the only allowed for that round? Specifically, can another non-clinician be able to submit a pre-application for a new full application?

Yeah, so we haven't had a discussion of that exact scenario. But as the primary intent of this is to manage the workload for scientific portfolio managers, I would say probably no you wouldn't get a second new non-clinician slot on top of the one who is resubmitting. I think as long as they're resubmitting that's going to use that slot.

Q: Could you confiirm - was it stated that a PI can only have one merit under review at a time?

I said they could only submit one per RFA at a time. And probably they'll be a limit of two. So one each under two different RFA's.

Q: There is a big difference in the number of Research Career Scientists in BL/CSRD vs RRD, with RRD having many fewer. Will this be the same moving forward or will the number of RCS become more standardized across portfolios?

Well so in the past there wasn't really good visibility across different services. So each service kind of made it's own decisions about what it was going to do and you know if there were 150 research career scientists in one place, and only 10 in another, you know there was no mechanism for that to be visible. So one of the purposes of the ISRM leadership council is to have more cross-portfolio visibility. So each of the career scientist programs will be managed by one of the broad portfolios. But they will be reporting up to the ISRM leadership council, what new ones they're funding and how many they have. So I think that this will stimulate a discussion about the role of research career scientist in each program. And what is the optimal size of that program relative to the broad portfolio goals. So I think you probably will see some changes but that's going to be slow. Probably will changes taking place over a number of years after we make the transition.

Q: Does the restriction of 1 proposal per site for non-clinicians only apply to proposals going to BLRD? Or also CRSD? (and does this include career development awards?)

Oh good point. It does not include career development. So new career developments are allowed. And they're not capped. And BL and CS are going away, and so it applies to the cycles that used to correspond with BL and CS. So the spring and fall cycles will have that restriction that summer winter will not.

Q: I had VA BLRD grant three times. I am a non clinician. Does the new procedure will allow me to apply or notas an approved non clinian application.

So if you are a funded VA non-clinician investigator then this only applies to new. The limitation only applies to new non-clinician investigators. So if you're already a VA investigator then you don't have to worry about this.

Q: Does the limit on one non-clinician submission per site only refer to corresponding PI? Could a non-clinician be mPI if they are not corresponding?

So maybe I'm not understanding the subtlety of the question. So if you are PI or multi-PI then that would count. So I'm not sure if that's what they're trying to get at. If you're a co-investigator on a proposal that somebody else is PI on. Then no that doesn't count.

Q: When will the pre-application approval be issued? How many weeks before the final application submission deadline?

I don't think we have a final decision on that. But we're trying to give people four weeks after they receive notification.

Q: Do you have an update of when the new RFAs / NOSIs will be posted?

September 3rd.

Q: Do you have any details on the pre-application requirements and due dates for CDAs? For those with approved LOIs, will the process be a formality, or will there be a full pre-application review (and potential for non-approval)?

The CDA due dates will be about 16 weeks prior to the final submission deadline in order to give us time to review and the applicants to make changes. The primary intent is to improve the applications not deny approvals.

Q: For IIR resubmissions, should investigators anticipate that resubmissions could be disapproved at the pre-application stage? (Or is the process primarily in place to transition to eRA?)

That is possible but I would think unlikely.

Q: Someone mentioned to me that CDAs may have a 5/8 requirement for submission — I believe this to be incorrect based on prior discussions and the slides that have been circulated — could you clarify?

They have to be at least 5/8 VA salaried at the time of funding. They don't require any 8ths at the time of submission.

Q: On the call, there was mention of only one non-clinician researcher applicant per cycle per medical center. Can you clarify?

For the **Spring and Fall rounds** there will be a limitation of only one **new** non-clinician researcher application per medical center per cycle.

Q: Will resubmissions all need to be reformatted to adhere to the new RFA requirements (eg, 19 page limit vs 14 page limit for CDAs)?

The current thinking is that they would have to meet the new RFA requirements.

Q: For hybrid title 38 investigators who are non-clinicians, is a waiver required for salary support on the grant? Additionally, can salary be requested above the budget cap?

If the investigator is funded at the time of application from the clinical appropriation they can not request salary on a merit or pilot award proposal. For investigators not funded from the clinical appropriation a waiver can be requested to exceed the budget cap.