"Sign PAF" Requirement for Investigators & "Other Support" Review – September 1, 2020

Introduction

Thanks for coming today everyone or for attending virtually. My name is David Mulder and I'm the program manager for international engagement and research security in ORSP. And I am joined today by April Pepperdine, who is the director of Conflict of Interest in the UMOR Conflict of Interest Office. And today we are going to be talking about some of the upcoming changes that are going to be happening along with the September release to the research proposal management system, eRPM. And also the new other support review that's going to be taking place in conjunction with those changes to the system.

Background & Context

So just to give a little bit of background on why we're making these changes. Many of you are probably already aware that there's been a lot of heightened interest in scrutiny, particularly at the federal level, in regard to foreign engagements and foreign activities and the need to minimize any risk of foreign influence that may result from those activities. So the January exercise that the university went through to update all of our investigators' other support documentation was one part of that. Many of you were probably involved in that or at least aware that that was taking place. And then a little while back, we also introduced a couple of new questions on the PAF related to foreign components. So that was another part of this effort. And now this new edition of the expanded Sign PAF activity and the Other Support Review are also parts of that overall effort to mitigate risks. And as I mentioned, these changes are going to be implemented on September 14 to coincide with updates to both the eRPM system and also to the M-Inform conflict of interest management system.

So just a little bit of additional background. I'm not going to read this, but I wanted to include it and folks can read it later on when, when we post the slides from this presentation. But I thought this was interesting to include because it's from the NSF, one of their recent updates

to their proposal, approval proposal and award - I'm going to get it wrong - processing guide, the PAPPG. And it's saying, can an authorized, how can an authorized organizational representative certify that its employees are making true statements regarding current and pending support based on that information not being available to the organization. And NSF has basically said, yeah, it's your responsibility, go figure it out. So that is in part what we are attempting to do here.

Assumptions, Caveats, Disclaimers, etc.

So just a few additional caveats and disclaimers. We are beginning a pilot phase on September 14 for the other support review. We are expecting to learn a great deal in the pilot phase. And so we expect that there will be tweaks and changes and modifications that will come as a result of what we do learn from the pilot phase. We don't have a set timeframe for how long the pilot phase itself will last. Because a lot of it is really going to depend on how many proposals that we see that need to be reviewed. So we're at the whim of the researchers a little bit.

Also in terms of the scope for what is changing in September, we are making changes to the PAF. And those will also affect just the initial award creation and setup phase. And include some manual processes for collecting this information post award. But we were actually really trying to limit the amount of system changes that would need to be implemented. Although I know our colleagues at ITS would beg to differ because it actually is, has been a tremendous effort on their part. And we're very appreciative.

We're also trying to limit as much as possible, at least during this pilot phase, the number of ORSP staff who will be involved. And as I mentioned, in terms of the volume, that's really what we're depending on here is the volume and also the complexity of what we see during the pilot phase. And that's going to play the biggest role in how we determine to proceed after the pilot phase.

And then Export Controls. The folks in the Export Controls office are also going to be leveraging the data that we are collecting with these changes to the PAF.

Terminology

All right, so that said I just wanted to review some of the terminology that's being bandied about. So we are in general talking about things that you could consider to fall under the umbrella of international activities. And underneath that umbrella, we have a couple of different terms that we've been using a lot lately, both foreign components and now international engagements, but they are quite different.

Foreign Components

So foreign components are related to where the work on a project is actually happening. It's project specific. It doesn't matter who is doing the work in regard to the project. And we are asking about foreign components in those still fairly new questions that were added to the PAF, it's question 5.13. And it asks if a significant amount of effort for the project will be happening in a, in a foreign location. And then if you answer yes to that question, then you also select the country or countries where that effort is happening. But as I said, that term foreign component is specific to the project and really has entirely to do with where the work for that project is happening.

International Engagements

On the other hand, when we're talking about international engagements, were talking about the resources and relationships that support a person's overall research endeavors. So it is related to the person. It's not project specific, it is anything that is supporting their research endeavors. And that information is what we are now going to start collecting on the Sign PAF activity, which we'll be going over in just a moment. And as I kind of alluded to at the beginning of the presentation, the reason that we have to collect data about these two different things is that in both cases, there are sponsor requirements that we disclose that information. And then we also need to review it in certain circumstances to make sure that any potential for foreign influence is being mitigated.

David, we have a question. Sherry wants to know what determines significant amount of work being done. That's the $1 million question, Sherry, and I'm sincerely not punting. But there is

information specifically regarding that question on the ORSP webpage for foreign components. In fact, it's almost entirely about making that determination. But, the short answer is that we are relying on information in particular that NIH has provided as to what they consider constitutes significant. But if you go to the ORSP webpage on foreign components, you can find that.

Process Touchpoints

Ok, so we're going to be talking about this new collection of information regarding international engagements really at three different points in the overall process. The first is at the point where the investigators sign on the PAF, and then the larger proposal submission period, and then finally at the stage of award setup.

PAF Investigator Signature

So beginning with the PAF investigator signature, just some overall items to mention about the new requirements. As of September 14, all U of M investigators who are listed on a PAF will be required to complete the Sign PAF activity. So basically, if you're listed on the PAF as an investigator, you're going to have to complete the Sign PAF activity. One of the biggest takeaways that I know April and I both really want people to get from this presentation - and that's why there's a little caution sign - is that in order to complete that Sign PAF activity, the investigators have to have an up to date M-Inform disclosure on file. And by up to date, we mean within the last 365 days. Okay. If you don't have an up to date M-Inform disclosure on file, the eRPM system is going to stop you. You're going to get an error message. We'll look at that in just a minute, but you're going to get stymied and won't be able to complete the activity. So please help your investigators as much as you can by letting them know that they're going to need to have that up to date.

The Sign PAF activity itself has three different sections. One is a confirmation of your outside activities, relationships and interests, and then a confirmation of your international engagements. And then finally, some language that is pretty similar to the existing activity today, which is the investigator signature attestation. And we're going to look at all three of those in a little more detail here. So to start with, when an investigator opens up this newly

revised Sign PAF activity. Like I said, if you - and these screenshots, by the way, are taken from a Google document. This is, we've been editing along with our colleagues in ITS to finalize the text. This is not what the system is really going to look like. So it's not quite this ugly. But when you, when an investigator does initially run the Sign PAF activity in the system, if he or she does not have an up to date M-Inform disclosure on file, they will get a warning message that says Warning you last disclosed in M-Inform as of whatever that greater than 365 days date is, or they'll get a warning saying you have not yet disclosed in M-Inform. In either case, they'll get this the bottom part of the red text there that says disclosure is required prior to completing the activity. Click here to go to M-Inform and then basically close this window and come back after you've done that.

Outside Activities, Relationships, and Interests Related to This Project

All right. Assuming that the investigator does have an up to date disclosure on file, then the next thing they'll see is this portion on outside activities, relationships, and interests related to this project. For those of you who are familiar with the existing Sign PAF activity in today's world where only the U of M principal investigators are required to run the activity. This language has not changed significantly. The biggest way it's changed is that in today's world, the principal investigator is actually answering this question on behalf of all of the members of the project team. And since we are now requiring all investigators to complete the activity, the language has been modified to reflect that it's only applying to yourself. And what am I forgetting? Oh, if the investigator answers yes to these questions about outside activities related to this project, than an additional text box will display, asking for some additional detail. And there was something else I wanted to mention. That again, as I mentioned earlier, international engagements apply to all of an investigator's research endeavors. They are related to the person in general. However, this question, again, is related to this particular project.

We have a couple of questions. So actually a lot of questions about PAF Sign. So one of the questions is from Vick. Do faculty receive an email if they do not have an up to date M-Inform before they need to sign a PAF. So, Vicky, that's going to depend. If they've never been in M-Inform before and the PAF will be the reason why they have to disclose, then no, they wouldn't have necessarily received that email. So there are a couple of things happening, could be at

the same time. If they already are supposed to be disclosing in M-Inform, they would receive an email at the first of every month asking them to go disclose. So they should have a heads up. So again, it's going to depend a little bit.

Heidi asks How soon after they complete M-Inform will they be able to sign the PAF. It should be instantly. They should be able to submit their M-Inform disclosure, go back into the PAF, do run the PAF Sign activity, and be able to sign the PAF.

And then can the PAF be signed by investigators in any order, or does the PI have to sign first? They can be the first or last. Can be signed in any order. It does not matter if the PI signs first or not. And can the PAF be signed before it is ready to route for internal approval? I don't know that answer. I am 99% sure that it can. Let me just - if Lynn or Laura could make a note of that just to get confirmation. But I'm almost positive that as soon as an investigator is added to the PAF, they have the ability to sign.

Okay. Any other questions? Oh, yes. One just came in. There are some personnel whose units include on PAFs as investigators, but who may not have to submit an OS (other support) document to the sponsor. Do these project personnel, then need to create an OS document for just for that internal congruence review. That sounds like maybe we should answer that one later. Let's hang on to it. We'll hold that one.

New International Engagements Questions

Okay. All right. Moving on then. So the second part of the Sign PAF activity includes the new international engagement questions. I will not go into these in a lot of detail, but you will have access to the slides after the fact so you can go back and review them when you have time. But basically there are four new questions being asked. The first one is, do you participate in a foreign international talent recruitment program? And there's a link there to the definition of that. The second one asks if you have an appointment, affiliation, or other relationship outside of U of M with a foreign entity institution. The third one asks if you have, if you're getting any monetary resources from a foreign entity, with the exception of grants, contracts or gifts that are awarded or given to U of M. And then the fourth one is asking sort of the same question, but in regard to non-monetary resources. So are you getting any non-monetary resources from

a foreign entity, for example, equipment, materials, or personnel that again, are related to your research endeavors. All right. And then let me flip back here one second. So if you answer yes to just question D. So D again is the non-monetary resources. If you answer yes to that question, then you will be displayed an additional textbox to provide some more details about those non-monetary resources. And then also a drop-down list to select the country or countries where those resources are coming from. Okay. The reason for the additional detail on question D and not the previous three questions is that there are essentially corresponding questions to those first three questions in M-Inform disclosure process. And so in theory, if you are answering yes to one of those first three questions, we should be capturing more detail about those things within the M-Inform system. Whereas for the fourth question, non-monetary resources, there is not an equivalent question in M-Inform and so we want a collection, collect data here instead. I will just add that ITS are building in a feature so that if an investigator does answer Yes to question, question D, non-monetary resources, enters text here and then finishes the PAF Sign activity, when that investigator goes in the future and goes to sign a different PAF for a different project, the system will auto populate whatever information they entered in the non-monetary resources textbox and the countries from their last time answering it. So hopefully we can save some time for investigators who would then not have to potentially repeat themselves from project to project.

There are a couple of questions coming in about communication with faculty. So will this information flow from you to faculty or are the research administrators expected to give them the news? So we do have a slide on communication and yes direct communication with faculty is occurring. Will there be an email sent to PIs that this is happening. Again, yes, that they need to sign the PAF and disclose in M-Inform if applicable. So just so everybody is aware, anybody that was listed on a PAF or award was newly required to disclose in M-Inform as of July 1. So if they're currently listed on a PAF or award, they're already in the M-Inform system and know that they have to disclose. It's just new incoming individuals that may not have had to disclose in the past.

If all co-PIs have not signed the PAF, can the PAF still be routed for approval? Yes. Yes. And is there a grace period for co-PIs to complete the signatures? So we have a slide on that. We'll talk about that one too, about timing of these requirements.

Attestation Statement

Let's see, I think we'll keep going now and OK. All right, then the next and final part of the Sign PAF activity is the attestation statement. Again, if you're familiar with the current attestation statement, in the Sign PAF activity, the language hasn't changed significantly. Again, it's mostly been updated to reflect the change from today's world where the PI is signing on behalf of the entire project team to tomorrow's world where an individual is attesting to these things just for himself or herself.

Okay. And another question, Beth asks are the resources on the previous question to be specifically related to the project proposed or just a general tally of any resources. So it's any resources. So for that international engagement question any resources. Yeah. Okay. Well, that's it for now.

System-Generated Notifications

All right. Okay. So then system-generated notifications. So the system, eRPM, will be sending out notifications to delinquent investigators. And those will start happening at the time that the proposal has actually been submitted to the sponsor. So starting one day after, and then 10, 20, and 25 days after the proposal has gone to the sponsor, any investigators who have not yet signed the PAF, who have not completed the Sign PAF activity, will be getting a system-generated notification. It's going to cc the PI and also the PAF's primary research administrator. And then at the 20 day mark, the message will also cc the department level research administrators. And at 25 days it will go to the unit level, which is sometimes referred to as the dean level, research administrator. So the idea being that as time goes on and we get closer and closer to the 30 day mark, the distribution lists widens.

And then the system-generated notifications that are sent out will also include this new email address PAF Sign questions that folks can go to if they need any help with anything. And just as a reminder, if they had not submitted their M-Inform disclosure, they cannot sign the PAF. So this will be the email that they will receive. This will replace previous emails that you may be aware of came from M-Inform asking individuals to go disclose if they had not done so specifically on PHS proposals.

We have a couple of questions. Let's see here. Will RAs be included in the general message being sent to faculty about this change so we can refer directly to communications? Do we know when the ITS Sign PAF documentation will be updated? So the first question was, will RAs be included in the communication or - yes - they will not be communicated, they will not be included in the actual communication going to faculty. There will be a RAPid going out that will be almost the same information. And we will link within that RAPid to the, to a web version of the communication that goes out to faculty. So basically you will have access to the message that's going out to faculty. So this email that we're talking about, the system-generated email, will any of the follow up emails include chair and/or CDA? No. I believe it's just department administrator. I believe it is just departmental administrators and then and then unit level administrators. Exactly.

And then what is the original communication to co-PIs that a PAF needs their signature. So it'll be the system-generated email after it's submitted. I think that the day after, they'll get an email indicating that they have to sign a PAF. And it would not come from RAs. It will come right from proposal management. And we'll get to the question about what happens if an investigator doesn't sign after 30 days or is that here. That is here. So the language in the system-generated email notifications does say that the proposal is at the risk of being withdrawn if all investigators have not signed within 30 days after submission to the sponsor. There is not, however, anything built into the system that will automatically withdraw the proposal at 30 days if everyone has not signed. But I would imagine that as we get closer to that 30-day deadline, more and more people will be discussing who still needs to sign and how we can make sure that everyone has signed. That's it for now.

Proposal Submission – "Other Support" Review Pilot

Okay, so then starting again during the overall proposal submission stage, we will be piloting a new Other Support review. And I just want to put out a caveat here that when we refer to other support, in this case, what we are referring to really is any type of documentation that the sponsor requires about an investigator's resources, affiliations, projects, that sort of thing. So in the case of NIH, we're talking about other support documentation. In the case of NSF, we're talking about current and pending documentation. We went back and forth quite a bit on what

we should call this in the system. And even amongst ourselves. And we finally landed on, let's just call it other support because it is the broadest sounding term that's being used.

So during the proposal stage ORSP and COI will review the other support documentation again or whatever the sponsor requires. And that function is going to be happening only if an international engagement question has been answered yes. So again, referring back to those four new questions on the Sign PAF activity, if any of those has been answered yes, and it is a federally-funded project, then it will fall into this category of other support review. At the PAF stage, including at Just-in-time, a small number of ORSP staff will be conducting that other support review. And for the purposes of the pilot at least, those ORSP staff are Tracey Larkin, Daniela Marchelletta, and myself. And then if sponsor documentation is either missing or incomplete based on that review, then ORSP will work with the project team to get whatever needs to happen updated.

Any questions April? Just one about reporting available out of BusinessObjects or eRPM for proposals pending investigator signature and those investigators who have not yet signed. Can, let's hold onto that and come back to it. I don't have a slide specifically on reporting, but I can address that.

Award Set-Up

OK. Then continuing. Now we're talking about the award setup stage. So at the award, the point of award setup, when the actual AWD record gets created in eRPM, there's going to be a new ancillary review requirement in the compliance status box. Most of you are probably all too familiar with what the compliance status box looks like. But I included a screenshot from just a sample project here of what that looks like. So there'll be a new row added to the compliance status box that will specifically say other support review. Again, if a project, if anyone on a project has answered yes to one of those international engagement questions on the Sign PAF activity and it is federally funded then that project will get a new row added on the compliance status box for other support review. And it will initially be set to the red stop sign. Okay. At that point, the COI staff will be conducting a congruency review across the information that was provided in the Sign PAF activity, so provided by the investigator in e RPM, what has been provided in their M-Inform disclosure, and then also what is included in whatever sponsor

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documentation is required. So for example, NIH's other support, NSF's current and pending, etc.

If the COI staff determine that there seems to be something lacking in the sponsor documentation area then they will ping our ORSP other support staff. So again, Tracy Larkin, Daniela and myself. And again, our ORSP staff will work with the project team to ensure that the sponsor documentation gets updated as needed. And once that has happened, then our ORSP staff will run a new activity in eRPM that will change the traffic light to green. And in addition, if the COI staff determine back up here at the beginning of the process, if they determine everything's good, no issues here, they also have the ability to just set it to green at that point and ORSP staff would never become involved.

We do have some questions, but they're not necessarily geared here. It's more about the requirement of other support. So we'll hold them, but we will come back to them.

And then a couple of other notes at the award setup stage. So investigators who are added at award setup will be required to complete a Sign Award Record activity. So this is again, if an investigator was not included in the initial PAF but gets added at the time of award setup. Then they will have an activity that is basically identical to the Sign PAF activity, but it's happening on the AWD record, So it's actually called Sign Award Record. And then we are also making updates to the Post Award Change Request form - the PACR - so that in the post award world, as an investigator gets added, we want to be able to collect this international engagement data from them. And so there'll be modifications made to that form as well.

Data Conversion and In-Progress Submissions

Okay, so let's talk a little bit about what happens then starting September 14 in terms of submissions that are in progress on that date. So on, starting on September 14, PAFs and clinical trial routing forms that have been routed for approval. so basically they are no longer in proposal prep, you have clicked on the route for approval activity in eRPM and that already have any applicable U of M principal investigator signatures in place will follow the old signature rule. So basically, you've gotten it out the door and had the required signers complete the Sign PAF activity using today's requirements, they will go through with no

changes. However, for anything that's created on 9/14 or has been sitting in proposal prep since before then, or does not have the required signatures in place, then the new rule will apply.

Some additional changes that are happening along with this. So for revised PAFs, in today's world, the PI only is required to sign on when a PAF gets revised. And starting with the September 14 release, PIs, investigators will no longer need to sign on a revised PAF. And that includes PAFs that are under revision as of September 14. For restored PAFs, and I know this is kind of somewhat confusing terminology, but a restored PAF is when something has actually been turned down by the sponsor or - I'm not sure if it includes withdrawn. Anyway, if it is restored, then the eRPM system will essentially strip all of the signatures off of that PAF and all investigators will be required to sign or resign depending on what the case is. And all awards will follow the signature rule that applied to their originating PAF.

Communications and Change Management

Okay. All right, then communications and change management. So the first RAPid on this topic went out on August 5. So if you were signed up to receive RAPids before that date, you should have gotten something in your mailbox already on this topic. The first targeted faculty email went out shortly after that, it went out from Mike Imperiale and Craig Reynolds. And that went out on August 13. The information included in those two messages was very, very similar. There is also a link available if you're interested in seeing the targeted faculty email. If you go to the ORSP webpage, there's a news item at the top of the site related to this release, and that can link you to that faculty email, if you're interested in seeing what they got.

There will be some additional details about this, particularly related to the Data Conversion and what's happening to submissions in progress that will be coming out in another RAPid and another targeted faculty email. Those will be going out next week. We have also been adding messaging both on the ORSP website and individual school and college websites, school and college newsletters, that sort of thing. And all of the existing job aids and training materials related to the Sign PAF activity are either in the process of being updated and some of them probably are already updated, and we will be providing links to those as they are available in

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those communications that are coming out. And also on the webpage devoted to Sign PAF on the ORSP site.

If you have questions or concerns that we don't address today, it's probably best if you use this new PAF sign questions email address. Right now that basically only goes to April, myself and also June Insco from the Med School Conflict of Interest Office. June couldn't be with us today because she's on vacation. But right now only the three of us are getting those messages. So that way, all three of us are in the loop. And it's great to hear your questions because what we hear from you, we can use to build out information on the webpage and the FAQ. And who knows. We might also factor it into what we, what changes we make to the system in the future.

So as far as what you can do, please spread the word to your investigators. And again, especially regarding that current M-Inform disclosure requirement, we really don't want people to end up getting aggravated when they go to try to do the Sign PAF disclosure only to get the error message that they don't have an M-Inform disclosure up to date.

Questions and Answers

All right. So what questions do we have left? Sure. So somebody asked, is there going to be another webinar available in the future on the same subject. This one is being recorded. So I don't know exactly what's happening with that, but I would assume it's available for people to view. But I don't, we don't have plans for another webinar, that I know of. If there's information that we did not cover in this webinar that you think could be covered in an additional one or in some other means, please let us know.

Okay, so I'm just going to head back up here and start asking some of the questions that were asked earlier. So Patrick asks, there are some personnel whose unit include on PAFs as investigator, but who may not have to submit an other support document to the sponsor. Do these project personnel then need to create an other support document just for the internal congruence review. Sorry, I was coughing and I missed the first part of that. There are some units who include people as investigators who are not required by the sponsor to provide other support documentation. Is that the gist of it? Yes. So you do not need to create something

special for this; the underlying purpose of the other support review is to ensure that the information that we're providing sponsors is accurate and complete. So if the sponsor doesn't require it, then you don't need to create something just for our sakes. And just as a reminder, it's only federally funded projects, right. So federally sponsored projects that we are looking at for the other support review for now in this pilot scope.

So the next question we said we would talk about - will reporting be available out of BusinessObjects that a proposal's pending investigator signature. So eventually the answer is eventually yes. We have a request queued up with ITS to get the data related to the investigator sign activity added to the data warehouse. I unfortunately, don't have any details on timing. But let me make a note of there might be some workarounds or alternatives we could come up with to try to make that information more easily accessible to folks who are looking for it.

Jennifer asks for review will ORSP request other support when PAF is submitted or are updated other support now required with PAF submission and or an SF 424. Can you repeat that one? Sure. She might have to unmute and help too. For review will ORSP request other support when PAF is submitted or are updated other support now required with PAF submission and or in SF 424. So I think what Jennifer might be getting at is are we going to ask for it at the time of proposal submission as opposed to just in time. And the answer is just in time. You will not, ORSP will not be requiring that you provide something earlier than what the sponsor requires it. So for example, NSF requires other support or their equivalent at time of submission, NIH would require it at just in time. Hope that answers your question.

Ok. Samantha asks what is the review time for ORSP staff reviewing other support for just in time. Typically, this requires quick turnaround time and we can need to be submitted day of. So the short answer is that for the purposes of the pilot, we are basically doing this outside of the ORSP timeline in terms of the review type and the deadline clock. So it shouldn't factor into that. I'm not sure if that answers the question. If it doesn't, you're welcome to unmute and interrupt.

So the next question, David says, if the proposal with international engagement is not federally funded, but a foundation, we still run through the system, or only if federal funds are involved. So for the pilot, the other support activity will only be required for I'm sorry, the other support review will only be required for federally funded projects or sponsored projects. However, the new PAF sign will be required for across the board. So any newly submitted PAFs will require all investigators to sign and answer the COI question and the international engagement questions. Hopefully that helps.

Let's see. So somebody said, it sounds like we should use the other support template that was completed in January since it's listing affiliations and outside support being requested. So yes, we would recommend using that template and that would be good.

Okay, there are more questions. Let me see what I get back into my space here. Is there another webinar? We answered that one. Reporting is there reporting. We can run of investigators who have not completed their up to date M-Inform disclosure. So the M-Inform system has department administrators and department reviewers. If you are a department administrator, you can look to see who has not completed their M-Inform disclosure. Right now it doesn't differentiate between if they have proposals or an award out there. So it wouldn't necessarily tell you if they are an actual investigator. Though we can look at that in the future. If you are not the administrator or reviewer, you can ask the administrator of your department for a list as well. I'm sure they would be happy to share that with you. Just to capture it, too, Patricia indicated that DoD also requests other support at time of submission. So again, it'll be dependent on the sponsor when other support will be submitted or the equivalent for that sponsor.

Cathy wants to know will a PAF still waiting for investigators signatures have a pending signature status. And where will it be on our home page? It will not have a pending investigator status. The signature on the PAF will not impact where it shows up in your inbox or which tab it shows up in any more than it does today. So it's the same locations as today's world.

And then Patrick wants to know if we were to add an investigator in the middle of the project period, does the new investigator need to sign the PAF and or have the congruence review to

be completed before we can add them to the project. So they would, they would need to complete the Sign PAF activity. His question was in the middle of the PAF. Is that correct? He said if a new investigator was added in the middle of the project period. So I would assume that means there is actually an active award. Oh, on an active award. And then the rest of his question was, does a new investigator need to sign the PAF and or have the congruence review be completed before we can add them to the project. So the short answer is, that information will be collected via the updated PACRs. So it will not be done in the system as of yet. And then we would do an assessment sort of outside of the system of whether or not there needs to be a congruency review.

Conclusion

OK. That's all the questions we have now, does anybody else have anything they want to ask? Just thank you's and nice job. So we can pause for another minute if there's anything else, but I think that should be about it. And I will just put in an additional request. These have all been great questions by the way. And these are exactly the kinds of things that we want and need in order to in particular build out the FAQ that we're creating on this topic. So if you think of additional things, don't be afraid to reach out to us because you're probably not the only ones. Otherwise. thank you everyone for attending today and hope to see you in real life at some point in the future.