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Session: The IRB Meeting - A Primer

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Soundia Duche: This ORPP&E led training will be on the IRB meeting, a primer. I will be one of your presenters. We have the pleasure of being joined by Ms. Eileen McCarthy-Dorsey who is an IRB administrator at the Philadelphia VA. And so she's going to be co-presenting and assisting us in today's presentation. So thank you Eileen, we're so excited to have you.

Eileen McCarthy-Dorsey: Thank you.

Soundia Duche: Also with me in the room today we have Lucindia Shouse who's with CSR&D and on the line in three separate locations we have Dr. Molly Klote, our director of ORPP&E, Dr. Karen Jeans, our associate director here in ORPP&E and then Dr. Kristina Borrer who's the Director of Policy and Education in ORO. And I stressed that they were in three different locations because they will chime in at different points whenever they want to add their perspective or give some clarifications, so we apologize in advance if on occasion we talk over each other ever so briefly. Just there's no other way for us to signal each other. But their mics are live and so they will in as they feel necessary.

So our objectives for today's training are to identify the key regulatory requirements to convene and conduct an IRB meeting. We're going to describe the best practices for preparing and conducting a convened meeting and then we're going to identify the key regulatory requirements that must be included in the IRB minutes. I'm going to stress the must part.

Now the mandate that I was given when I was asked to create this training was to arm the field with the knowledge of what is required to prepare effective and compliant IRB meeting minutes. And so in thinking about how best to accomplish this task I actually recalled an analysis that I had done way back in 2011, for the VA Central IRB. I am a regulatory advisor for the VA Central IRB and so many of the examples I draw on are from my experience with them and the tools they use.

But back in 2011, the VA Central IRB, while their minutes were compliant, they were struggling with the length of the minutes. They had extremely long meeting minutes, as well as the time it took to create those minutes, okay? And so they wanted to identify where were the hold ups, what could be done to improve the effectiveness and efficiency of their IRB meeting minutes. And so I conducted an analysis of almost all of the minutes. I interviewed the staff, talked with the IRB administrator. And in the end we identified about ten bottlenecks that were directly impacting the effectiveness of the meeting minutes and the time it took to create them. And when I categorized those, they fell into three discreet categories. They fell into tasks that were done pre-meeting, tasks that were done during the meeting and obviously tasks that were done post-meeting, which is your actual preparation of the meeting minutes letters. What was very surprising is the one bottleneck that, there was one or two, but one in particular that had the most significant impact on the meeting minutes in terms of length and the time it took was an activity that occurred pre-meeting.

And so what our goal is today, we want to provide you with both the knowledge of what has to be done during a meeting and what has to be included in your meeting minutes. We want to arm you with tools though that you can use to collect that information, collect the necessary information you need, track the various things you need to track and in the end have effective and compliant meeting minutes. For those of you who are new, this will be a complete primer and we're going to expose you to a lot of things that will result in effective meeting minutes. For those who have been at this game for a while, by the end of it hopefully you'll walk away with hmm, these are some things that maybe we want to reconsider. We have this problem, you've identified, we've helped you identify what may be causing it and so you can go back now and figure out how best to improve your process.

So before I delve into the details, I want to ask Eileen, can you spend just a minute or two telling people about yourself and what you've been doing all these years with IRBs.

Eileen McCarthy-Dorsey: Sure. Okay. Thank you Soundia. I've worked in the research world for about 30 years, more than half that time as an IRB administrator. My career has taken me from Temple University, which is where I started with research, to Drexel University and now to the VA. I've been at the VA for almost 15 years and counting. At this point, I have looked at the IRB as a career more than a job. It's always been interesting and exciting. It can be very challenging with the rules, regulations and all the personalities that come with IRB. But I've always found it rewarding and always a new experience which is I guess why I've stayed with it for so long. You don't want me to go any further.

Soundia Duche: [Unintelligible 05:26]

Eileen McCarthy-Dorsey: I could go on all day.

Soundia Duche: Okay. I appreciate all the insight you're going to share with us. Eileen is going to be sharing some real life examples of what they do at their facility to illustrate some of the issues we're going to encounter.

So let's start with pre-meeting. Eileen, how often does your IRB meet and how large is your board?

Eileen McCarthy-Dorsey: Okay. So we have two IRBs here. I handle IRB 1. Each IRB meets once a month. I'm only going to talk about IRB 1 because they're my experiences. We have 13 voting members and I have always been very lucky since I've been here that my members have been very committed to the IRB. And most of us have been together for almost 15 years on the same IRB.

Soundia Duche: And so then in preparing for a meeting Eileen, how do you ensure that you're going to have sufficient members present at the meeting?

Eileen McCarthy-Dorsey: Well I start by sending an email to my members one or two weeks ahead of time, just as a reminder and let them know what they should expect on the agenda. And then I also have a sign-in sheet. And I pull that up and as individuals say yes, I'll be there or no, I won't, I start marking it off immediately. And then as we get closer to the meeting date, if I think we're in trouble, I send out another email. And remind everyone. But I can truly say I can count on one hand how many times we've ever had difficulties obtaining quorum.

Soundia Duche: Okay. And so I like\_

Eileen McCarthy-Dorsey: [Unintelligible 07:06].

Soundia Duche: Yeah. You are. You used the term, quorum. And this is key because one of the first tasks when one is preparing for a meeting is making sure that you will have the necessary members needed in order to achieve quorum, okay? Any IRB has voting members, they have non-voting members. Some IRBs use alternates. Alternates are members who can take the place of a voting member and they're particularly helpful if a voting member can't be there or if a voting member had to recuse themself because of a conflict of interest. You may also have guests attending and so all of these things you want to factor in and track. If you have observers attending your meeting or if you have the study team calling in. All of this information you want to be able to track and manage as you approach the meeting date. For members who have a conflict of interest, that's something you want to ask them way before the date of the meeting because again, in trying to figure out if you're going to have sufficient members to conduct the meeting, you want to be able to identify who has a conflict of interest and in what study. If a member has a conflict of interest they cannot count towards quorum. They have to recuse themselves and leave the room or exit the telephone call if they're on a call, and they cannot count towards your quorum.

And so quorum, I keep saying that. Quorum is the minimum number and type of IRB member that must be present at a convened meeting for the IRB to conduct its business. And so when you're calculating what your quorum is, each IRB will have a unique number for their quorum. Quorum is calculated by the majority of voting IRB members on the IRB roster. And it has to include a non-scientist, okay? So the majority. If your IRB roster is a certain number, ten voting members, your quorum is calculated based on that roster. And it has to be a majority of voting members to include a non-scientist. How you define majority for our purposes, we're going to use simple majority throughout this meeting. A simple majority is strictly more than half. More than 50%. But really in your SOPs, you should specify how you define majority so that if an auditor comes, there's no question about if your IRB, when making its votes, were making it under a quorum, okay? If you have achieved quorum. If you cannot maintain quorum, or if quorum is lost at any point in the meeting, no review, discussion and/or vote of a proposed research action can take place. And so this is why it's so critical in your planning phase to be able to anticipate how many members you will need so you don't “get yourself in trouble”. Find yourself in a situation where in the middle of the meeting you lose quorum. You fall beneath the number of that simple majority, in our case we're using simple majority, but however you define majority, okay?

One thing that people sometimes get confused of, if a member is, a voting member is present at the meeting but chooses to abstain from voting on the item, they still count towards quorum. Okay? [Unintelligible 10:23-10:26], but they still count towards quorum. It's when a member has to recuse themselves because let's say they have a conflict of interest, or they have to leave for any reason, if they have to leave the room and do not come back before the vote is taken or just forget, they just leave the room, if you lose quorum at that point because a voting member has left the room and you fall below the number required for quorum, no additional business can be conducted. So very important to plan and anticipate in advance so you don't find yourself in that situation.

So some examples, just to illustrate this further. For an IRB roster that has ten voting members, using the simple majority calculation of quorum, you would need at least six voting members, one of whom is non-scientist. Quorum for that IRB is six. That's over 50%, that's 60%, right?

If an IRB roster has seven voting members, again using simple majority which is just over 50%, you would need at least four voting members, one of whom is a non-scientist, all right? 50% of seven is three and a half. And we understand, we can't really have a half a member right? But if you go up to four members, that's actually 57%, that's over half. So if you're using simple majority and you specified that in your SOPs, then four members would be over half. And so four members would be the amount for an IRB roster of seven voting members. That would be quorum using simple majority calculations.

Again, I want to stress, if after meeting you only have four voting members and your quorum is four, you're finding yourself possibly in a potentially difficult situation because if one member has to recuse themselves due to a conflict of interest, or fine, let's just say they told you ahead of time, there are no conflict of interest, but life happens. Something happens during the meeting and you have one member who has to leave for whatever reason, all business has to come to a complete stop. The IRB cannot continue deliberations unless they have another alternate member who can vote in place of that member, who has been designated as a alternate for the member who has left. So a lot of planning needs to go in place to make sure you don't find yourself in the precarious situation whereby the IRB cannot conduct its business because of failure to maintain quorum.

So we have some polls here, just two. I just want to make sure for people who are more new to this, how to calculate quorum. So in this example, we have an IRB that has 11 voting members on its roster. Our question is, what is the number of members required for quorum using the simple majority calculation. Is it four, to include the non-scientist? Is it five to include the non-scientist? Is it 6 including the non-scientist or is it 11 including the non-scientist? Eleven voting members on its roster, what is the number required for quorum? Four, five, six or 11? And Erica, if you could pull up the poll.

[Pause 13:44-14:35]

Erika: Okay. So it looks like 4% say option one, 7% say option two, 86% option three and 3% option four.

Soundia Duche: Excellent, thank you Erica. And the right answer is, 86% of you got it, six. Option three. Six members including the non-scientist. That would give you 54.5% and I did my calculation ahead of time. But again, using the simple majority of over 50%. So six. All right. Let's try another one just to make sure. Going to get a little bit more complicated.

The IRB total membership for this particular IRB is eight voting members prior to the convened meeting today on May 31st. The quorum is five, okay? Including the non-scientist voting member. Now we're at the meeting. Everything is going well. Well, up to a point when all of a sudden, one of the members, a scientist in this case states he or she no longer wants to be on the IRB and is quitting immediately. And in fact the member leaves the convened meeting. And so the question is, has the number of members required for quorum changed for the remainder of the convened meeting? And remember, quorum is the minimum number and type of IRB member that must be present at the convened IRB meeting based on your roster. So has the number of members required for quorum changed for the remainder of the meeting when that scientist decides to leave? And responses are yes or no.

[Pause 16:16-16:38]

And remember there were eight voting members prior to the meeting. Quorum was five and there were five in attendance before the scientist decided he was just done, he'd had it and left the room.

[Pause 16:50-17:10]

Erica: And Soundia, it looks like 55% say yes, 45% say no.

Soundia Duche: All right, okay. So what's going on here? Quorum is based on the roster, right? Just because that member has decided he's quitting immediately and he's left, he's no longer part of the IRB, that roster has not changed. He is still on the roster. And so the correct answer is, the number of members required for quorum hasn't changed. There still has to be five voting members in order for the IRB to conduct business. But, and I think this is where people were going for, the IRB has lost its quorum, right? It cannot achieve quorum when that member has left. And so business cannot continue, okay? So really want to drive home the point. The number required for quorum is based on the roster. That number doesn't change. The ability of an IRB to achieve quorum, that changes all throughout the meeting as people go and come, recuse themselves and so on and so forth. And I just want to say, that member, I'm sure this never happened at anyone's institution, but that member who decided to up and leave and quit, they were probably just looking for an excuse to do so and they had made that decision and the first opportunity that they could leave the IRB they took it. So that's just an aside.

All right. So now we've already looked at, we have a good idea of who we expect to come to the meeting. We've made sure we have more than enough non-scientists, more than enough members for quorum. We're not operating too close to quorum. And so now we move on to creating the meeting agenda, okay? This is where determining when a study should be placed on the agenda is really critical to the success of your meeting, how the discussions go and ultimately to how effective your meeting minutes are. And you can tell right away based on the meeting minutes, based on how long they are, based on the number of modifications, whether a study was ready to be placed on the agenda. And so Eileen, how do you all determine when a study is ready to be reviewed by your convened IRB?

Eileen McCarthy-Dorsey: Okay. Well we have a specific deadline, a specific IRB submission deadline which is always the third Monday of every month. When a submission comes in, I go through it to determine if all the required materials and signatures have been submitted. If everything is in order, I give it to my chair. I give the abstract, the protocol summary and the consent to my chair and he determines whether it's actually expedited or full. So then we move on forward. However, if the submission comes in and it is in such a way, in my opinion, that our members would have a difficult time reviewing it, it goes back to the investigator, explaining the deficiencies and telling them that the study would go to the following month's meeting.

Soundia Duche: Okay. And many people do what Eileen does. They have this pre-specified cut-off date that they publish on their calendar on the web page and most study teams know that if they get their documents in two weeks before the meeting date or whatever the cut off is, I have seen cut offs one week before the meeting date, then that study will go to the convened board.

An alternative approach that some IRBs use is that they require at a minimum an administrative review by their IRB administrator or managers, or even the primary reviewer for those institutions that use a primary review, they require the primary reviewer to perform a review and send those comments to the study team. And they will specify in their processes if the study team has to respond back to those comments and revise the documents before the study gets placed on the agenda or if they will just proceed with placing the study on the agenda knowing that they sent the comments in.

I will say that there are some benefits to not having a pre-specified cutoff date and I'm going to use the VA Central IRB example again and Annette said I could share this with you. But back in 2011 they did have a pre-specified cut-off date. And when you have published a date, everybody understands that as long as I can get my study in, it will go to the board. And so there's a pressure that even if a study isn't ready, you feel pressured that it has to go to the board. And when I say ready what I mean is, is it clear? Are there are a lot of inconsistencies? Are there things missing? The IRB cannot conduct its review and make its determinations if they can't even figure out what's going on, if they don't have the right additional information to make their determinations. And so in the VA Central IRB's case over time now they have gone away from pre-specified cut-off dates. The meeting dates are published, they do two meetings a month, but there's no cut-off date by which you are guaranteed your study will go to the convened board. In their case, the manager performs an administrative review and they have their reviewers, they use a primary review system. They have their reviewers, their ISO and their PO all perform a review. All the comments are bundled. They're sent to the study team and the study team has to address them, revise the documents before the study will be placed on the agenda for the next convened board. And the reviewer will look at that, look at the comments, make sure that the protocol on all the documents are in a state where the IRB can make an effective decision. And that doesn't mean that there still aren't issues that have to be resolved, but it means that at least the protocol is in a clean state so that the IRB can conduct their review and perform their functions. And in fact, when I looked at the meeting minutes back when I did that analysis, that was one of the most fundamental issues that was resulting in very long meeting minutes and then subsequently we realized lots of deferrals. Protocols that weren't ready to be reviewed by the convened board, that were placed on the agenda prematurely, got deferred once, sometimes twice. And so essentially it created a lot of work for everybody.

So different approaches. What we're just trying to show you is there are different ways to approach determining when something is placed on your agenda and if you are having problems, you might need to revisit your approach. Okay? The order of the agenda is something that you also might want to take into consideration. We'll talk a little bit more about that later on where I'll have Dr. Klote share with us what she thinks is an ideal order. But I just want to say that there are going to be a lot of competing forces for how things should be placed on the agenda. You're going to have continuing reviews that have to be done by a certain date. You're going to have reportable events that have to be reviewed by a specified time frame. The reviewers availability, whether they can stay for the meeting. Study team. If the study team is going to be invited. So all of these things have to be taken into account when you're deciding on the order of your agenda. And Eileen, I want to ask you, do you all invite your study team to meetings? And if so, does it work well? Do you feel it's a benefit to you?

Eileen McCarthy-Dorsey: Yes, we do invite them. We always invite the investigator and if he or she cannot attend, we ask for a member of the study team who is knowledgeable about the study. And if they cannot send anyone, we have deferred the review of the study to the next month. The committee, the IRB finds it very helpful to have the PI or the study team there to ask questions I don't necessarily have to go into for the minutes. I mean just sometimes you just need a little bit of clarification. For me, I like it because then I can put the names and faces together and have a better idea of who I'm working with.

Soundia Duche: Gotcha. Thank you, it's very helpful. So I want to touch briefly on expedited listings for those institutions that use the expedited review process. The common rule does require that the IRB has a method in place, normally you specify this in your SOPs, of how you're going to keep all members advised of research proposals that have been approved using expedited review. And normally this is for any action that's approved under expedited review you have to inform the entire IRB. In VHA Directive 1200.05, the policy requirement is that you include in your SOPs how you plan on informing all members, investigator and the R&D committee of the decision, the expedited review decision. You have to include the expedited review eligibility category as well, okay? Prior to the revision of VHA Directive 1200.05, there was a requirement that the expedited listing had to be communicated to the IRB at the next convened board meeting. That specific time frame has been removed. And even just the whole way that the IRB chooses to inform an investigator, we've opened it up to allow sites more flexibility. But what you put in your SOPs is what you'll be bound by. And most people haven't changed that because it works for them. You know, sending it to the convened board. I'm sure most people have removed the time frame of that next meeting, but again whatever you put in your SOPs is what you'll be held to. Eileen, for the expedited listing, do you all still distribute it at the convened meeting?

Eileen McCarthy-Dorsey: What we do is we put it on our agenda and report yes, we report every expedited, actually we report everything that we do is on the agenda and at least gets reported to our members. And then we place, we have a specific statement that we put in our minutes that the study was reviewed, expedited by the chair and a co-reviewer for the month and then we just report it to the full subcommittee. And that's in our agenda. And then it also goes in to our minutes as well.

Soundia Duche: Okay, perfect. By sending it to the convened board, it's a perfect opportunity for everybody to just take a moment and spend some time looking at the expedited listing. Members can raise questions at that time. At a minimum, you see a couple of things that should be included in your listing, the protocol number, title, PI name, category, expedited category as well as the date of the approval. It is also very helpful to include just a short summary of the action. You know, something as simple as, approved minor change in informed consent document. Something so that the reviewers who had nothing to do with that study, when they're looking at the expedited listing, it means something to them. And therefore if they have further questions they're able to ask by being able to see a little short summary of what the action was.

Eileen McCarthy-Dorsey : Soundia, excuse me. We actually do that as well. We put a brief, the purpose of the study, brief explanation so our members see that.

Soundia Duche: Excellent, great. And so now, in terms of the tools, what tools do you all use? Or you do prepare prior to the meeting, Eileen, for use at the meeting. What have you found to be helpful?

Eileen McCarthy-Dorsey: Okay. So what we use. We have what we call a primary reviewer checklist. And before we send our studies, specifically initial expedited and full reviews, I prepare the primary reviewer checklist. I put the reviewers name on there, the PI's name, the study title. And then I send the primary reviewer checklist and the entire IRB submission package to our reviewer. He or she then goes through the IRB submission package and what we've done with our primary reviewer checklist, we have married the two documents. So our reviewers go through the checklist and our submission package and can go section by section to determine that each element has been met in that study. The reviewer then gives back the completed and signed checklist to me and it becomes part of the study folder. They put in comments if they have any. Prior to the new common rule, so 2018 or pre-2018 we did it a little bit differently. Our primary reviewer checklist was actually distributed to the investigator and his or her research staff at the meeting. The form was a little different then, but with all the new regs we've changed a little and cut down on the amount of paper that we've been distributing.

Soundia Duche: Gotcha.

Eileen McCarthy-Dorsey: Our checklist is more for us now. It's more for the IRB. It's not necessarily for the investigator. It helps us determine how any stipulations that might be needed.

Soundia Duche: And it's part of your documentation. It counts as your documentation for determinations and actions supporting the IRB.

Eileen McCarthy-Dorsey: Yes.

Soundia Duche: So that's important. So a couple of examples of tools. I'm not going to spend much time going through this, but just want to point it out. It's something for you to use and tweak to your liking. But in addition to the reviewer checklist that Eileen mentioned, the VA Central IRB has an agenda tool. This is something that's prepared by the IRB managers for each study. It's specific to the study and what it does is it goes through all of the required determinations the IRB would have to make for that study.

So for example looking at the bottom number eight, drugs and devices. If it was an FDA-regulated study, that box would be filled in to alert the IRB that they have to make the necessary determinations. If there was a request for a waiver of HIPAA, that box would be highlighted or checked in saying yes, or waiver of HIPAA for recruitment requested or whatever it was. And so when the IRB makes their motion and they're going through to determine if all the approval criteria are met and all the determinations they need to make, they use this tool to help guide them. To make sure they haven't missed anything specific to that protocol. Again, just an example of something you might find helpful.

Another example just wanted to share is voting matrix. Now for those of you who have an electronic system, kudos to you because I'm sure it really helps in tracking the members, who's voting for what. Probably can split the members, select the members that will be attending the meeting, select the agenda items and you might get a nice pre-filled matrix. The VA Central IRB doesn't have an electronic platform, so prior to each meeting they complete this, they prepare this and it helps them be able to say for each agenda item reviewed, each voting member you see, one to ten is listed. They have the names of the voting members whether they voted for, against or abstain. And again, all of this will help later on when you're writing your meeting minutes and documenting how many members for, against, abstain. If the member was not available, if they had recused themselves, all of this can be filled in. So this becomes a very powerful document to help in the preparation of meeting minutes. And also making sure that you have maintained quorum and recorded your votes correctly.

All right. So let's move on now to the meeting. We've done all our preparation. We’ve anticipated who's coming, we'll confirm right? We'll confirm COIs, we'll confirm whether we have alternates attending in place of members. We'll confirm if we have alternates attending just because they won't be voting for anybody. We have our voting matrices and everything that we're going to use to track things. There will be a lot of logistics and tracking that you'll be doing at the meeting. Some sites choose to record, some don't. Eileen, to record or not to record? Which way do you go?

Eileen McCarthy-Dorsey: Record! I am a believer in recording especially when you have initial reviews that have to be done by the full committee. They're the ones that can be the most confusing especially if they involve drugs or devices. The down side to recording is if you have a meeting that goes for a couple of hours, you may be listening to it again for a couple of hours. But, what I do so I don't have to concentrate on the entire recording is I make notes on my copy of the agenda as we go along so I know where I need to really pay attention to those recordings. I'm a firm believer of recording. I think it's a great thing.

Soundia Duche: There's no issue with recording, but just as long as people know this does not circumvent the need to have written meeting minutes. You have to have written meeting minutes. So you can use a recording in addition to your handwritten notes if that suits you. But in the end, when you're creating your meeting minutes, you have to have written meeting minutes documenting, at a minimum, the required determinations, okay?

During any meeting you're going to have a lot of other miscellaneous things. Announcements, reviews and vote on previous meeting minutes. We included this because we just wanted to point out to folks that there is no regulatory requirement to approve or vote on meeting minutes. Your local SOP will dictate your process. Many IRBs state that they will approve and vote on meeting minutes. Not a problem, but just wanted to let folks know you do not have to unless your SOPs say that you will. Same with the review of expedited listing. In terms of how you do it, you do have to send it out right? No ifs, ands or buts. All IRB members have to be advised of all actions that were approved under expedited review. But in terms of when that goes out, how it goes out, does it happen at the meeting. All of that will be dictated by your local SOPs. And then just lastly, for those sites who do invite the study team to call in, just remember to keep track of the time because sometimes you end up having to move things around because your review went longer than you thought. So try to give your study team a large window. Don't get too specific. Yeah, it's inconvenient to give them an hour window, maybe 30 minute, maybe 45 minutes. But give them a window to allow yourself flexibility in case you find yourself running over.

Now, the order of items on the agenda. This was one of the things again, there's going to be a lot of competing forces that you're going to have to factor in. But experience has shown that it really is important to focus on your existing book of business before new business. Now I'm going to ask Dr. Molly Klote because of her experience as an IRB chair, to give us a perspective on an ideal order of items on the agenda that's displayed here.

Dr. Molly Klote: Right thanks Soundia. So a lot of people set up their agenda to take care of new studies first and as a chair there's nothing more frustrating than getting close to the end of the meeting time because you've spent a lot of time on a new study that maybe needed a lot more discussion than you had anticipated, and then it comes down to doing continuing review and you're rushing through your continuing reviews and you're really not putting in the time and energy that you should be, or that the board should be. And so years ago we reorganized and said look, we've already committed to the protection of the human subjects in these particular studies that are within our portfolio. We need to spend the appropriate time and energy on them before we add something new into our portfolio. And so we would start with continuing reviews and then deal with amendments and then handle reportable events. Then we would take back on re-reviews of protocols that we've seen previously because a lot of those can now be under time pressures because we did push them off for a month because either they weren't, we didn't have enough information to review it or we had run out of time in our previous meeting and then we get to new protocols. And you really do try to get to the new protocols that are scheduled right? But I think the, in an ethical framework, taking care and really doing the reviews of the things that your institution has committed to is really important. And I'll leave it at that. Over.

Soundia Duche: Excellent. Thank you Dr. Klote. All right. So these next two slides I'm really not going to spend much time on because you have the information here. But I do want to talk about this first item, okay? From new protocols and amendments, the IRB has to make various determinations. How you record them, where you record them, we're going to go into what has to be in the minutes versus what can be in the minutes or some other places. But the IRB discussion of items to include controverted issues and their resolution is something that is key and critical and has to be documented in the meeting minutes, okay? The discussion of controverted issues and their resolution. And it's something that people aren't as familiar with because honestly you don't see it that often. You're not going to have a controverted issue for every study. You're probably not going to have a controverted issue in every meeting. But with that said, what is a controverted issue? These are things where there's disagreement and dispute. There's a lot of back and forth. It doesn't have to be someone raising their arms and leaving the room. It could just be a debate or just a disagreement where people have strong feelings that no, they feel this is not the course of action the IRB can take. And it can just be one person. It doesn't have to be the majority. It doesn't have to be a few members. It can be one person who feels strongly on a different course of action. And so you must include in your IRB minutes, the discussion of controverted issues and their resolution.

I recall in one of the meetings back when I was an IRB administrator before my VA days, we had a meeting, I can't remember the specifics but there was a big discussion about, I think it was a requirement for something that should be done for the investigator, the study team. Maybe it was a mentorship. Some of the members felt they needed mentorship. I can't remember. But one member in particular felt very strongly against the course of action the majority wanted to go. And he actually left the room. He was quite a spirited member. It's always interesting when you have spirited members. But you know, he left the room and that was his prerogative I guess, to leave the room. Certainly his prerogative to voice strongly his feelings though. So that would be something we would capture in the meeting minutes of there was a controversy, this one member left, and you don't have to name names, but this one member felt strongly that dot dot dot dot dot. And this is how it was resolved. And sometimes the resolution is simply, the majority voted to proceed. And you've noted the controversy. Eileen, do you have any examples in your experience?

Eileen McCarthy-Dorsey: I tend to agree with you. We've had very few controverted discussions. I'm happy to say nobodies ever stormed out of the room. And nobody has ever gotten to that point, that's always a good thing. And we agree and I agree majority rules. If a discussion keeps going round and round and round and you're getting nowhere, you need to take a vote because nine times out of ten it is only, and I don't mean that it is only one member, because everybody's opinion counts, but if only one individual has issues with the study, you need to go with the majority. And document you know. Document, document, document. But majority does rule.

Soundia Duche: And so that's one of the determinations that has to be in the meeting minutes. We'll talk later on about the ones that have to be in the meeting minutes. These are other determinations that the IRB has to make. I'm not going to go over all of them, but they're here for you to refer to. The risk level determination of the study, whether it's a device, significant risk or non-significant risk. The 111 approval criteria, so on and so forth. If they're vulnerable populations certain determinations are required. If the IRB requires modification, that's something that is required to be documented in the minutes. You could document elsewhere as well, but it is required in the minutes. The approval period, frequency of continuing review, reasons for deferrals or disapprovals. All of these things are determinations the IRB has to make. And a lot of times that's done in concert with a protocol that goes to the convened board. That some of the items will be discussed, some of them the reviewer has already taken into consideration on his reviewer sheet. So that item might not be discussed at the meeting because the determination was made and the IRB then either answers yes, we agree with you on x, y and z.

Once the discussion is done what happens is there's a motion. Usually somebody will propose a motion, an action, and then usually someone else will second it and then the IRB will vote on it. And so, in terms of actions, there are multiple actions an IRB can take. Approve a study outright, they can approve it with conditions. People call this different things. Some people call this approval with minor mods. However you define it in your SOP, but essentially what you're saying is, the IRB feels that if they make certain very direct stipulations and the study team follows those direct stipulations, then all approval criteria can be met and there's no need for the study to come back to the convened board for review. So whatever terminology used, that's what we're talking about. That process. And normally your IRB minutes will specify who's responsible for reviewing the response that comes in, or in your SOPs you may just say, all responses will be reviewed by whoever. Maybe it's the chair, however you do that, okay? The IRB can require modifications to secure approval. What that category means is essentially the IRB cannot make all the approval determinations at this time. They need the investigator to modify and respond to certain things and they need to review those responses. They have to come back to the convened board. The IRB can suspend, disapprove, terminate. These are just different actions the IRB can do. Some of you will use the terminology defer, table. It's very important in your SOPs to define how you're using these different things because for one IRB a deferral is similar to what another IRB calls table. So again, what you write in your SOPs is really what you're going to be held to.

So somebody will make a motion and then the vote will take place. Now only voting members can vote on IRB actions, okay? An alternate that's substituting for a voting member can vote, but it can only be voting members. And this is where the matrix or something similar is very helpful. Members that are absent who have comments and opinions that they want to share with the board are more than welcome to send, those comments can be sent in. There's nothing wrong with that. Sometimes you maybe even have the primary reviewer who did the review but for whatever reason can't attend the meeting, they want to send in some comments. Those comments can be read and shared by the board, but that member cannot count towards a quorum. They cannot participate in the vote. They cannot send their vote in and they cannot vote essentially. But so the vote takes place and when you're voting for a motion, in order for that motion to be approved there must be at least a majority of voting members have to approve the motion. So if ten voting members are present at the time of the vote, in order for that motion to go through using simple majority again you would need at least six of them to vote for the action. And again, remember our voting matrix nicely laid out. You can record who voted for, who voted against, who abstained and if there's a COI or someone is not available for whatever reason you would cross them out and say left the room at this time, came back, or however you want to do it. But again, tracking your votes is very important. We're going to do two case studies on voting to make sure we can drive home the, how voting is done.

So our first one. We have 15 voting members present during the review and vote of a new study to include two non-scientists. So this IRB is prepared. They have two non-scientists. They have 15 voting members. Their quorum we're told is 11. So they've allowed, they have some flexibility should some members have to leave for various reasons. But in this particular item no conflicts of interest have been declared so all 15 members are present. A motion is made to approve the study. Our question is, what is the minimum number of members that must vote in favor of the motion for the study to be approved? Fifteen voting members, what is the minimum number of members that must vote in favor of the motion for the study to be approved? And your options will be eight, nine, ten or 15. Erica if you can pull up the poll.

[Pause 49:00-49:49]

Erica: Okay Soundia. It looks like 81% say eight, 11% say nine, three for ten, 5% for 15.

Soundia Duche: Awesome! Eighty-one percent of you were right. Eight, okay? Eight divided by 15 is 53%, simple majority. Remember that's what we're using throughout this training, okay. So over 50% of the members that are present have to vote to approve the motion. If less than eight voted, that motion would not have been approved and at that point the IRB could propose another motion or figure out what they're going to do. But that motion as proposed would not have been approved if less than eight people had voted in favor of it.

All right, last case study. The next item on the agenda, same board, okay? The next item on the agenda is a reportable Serious Adverse Event. There are 15 members present for this action including two non-scientists. Our quorum is 11. Now, one non-scientist member receives an urgent call and has to leave the room during the discussion and does not return to the meeting. Okay, so we started with 15, one has to leave urgently. Another member who's a scientific member declares a conflict of interest and recuses herself from the entire meeting and also does not return. So we started with 15, we've lost two. A motion is made that the reportable event is not serious and/or the incident was not related to the research. All right? So the question is, what is the minimum number of members that must vote in favor of the motion for it to be approved? Seven? Eight? Nine? Thirteen? Or the vote cannot take place. So just to remind people, we started with 15 members, we lost one non-scientist to an urgent call. We lost one scientific member to a conflict of interest. Of our 15 members we had two non-scientists to begin with. All right. Erica, if you can pull up the poll please?

[Pause 52:04-52:58]

Erica: Okay, here are your results Soundia. Most people said seven, 33% at eight. Four percent, nine. No one picked 13, but 8% said the vote cannot take place.

Soundia Duche: Okay. All right. So the correct answer is seven. Now why is that? We started with 15 members. We lost two so we're down to 13. Okay? So 13 is the number of members that are present for the vote. We were told our quorum is 11, so we have more than enough members for quorum. We have 13. And while we lost one scientist, remember we were told we had two scientists, so we still have our non-scientist. So we lost one scientist and we lost one non-scientist. So we still had one non-scientist. So we have 13 members. Sorry for those who just lost my recording. Okay. The vote can take place. So if 13 is the number of members that are voting, in order to approve the motion using simple majority, we would need at least seven members to vote in favor of the motion. Seven divided by 13, I calculated it before, it's 54%. Okay? We're over 50. So that's how that was calculated. Again, this is where the voting matrix comes in handy because as you start going through and people start leaving for different reasons at the last minute, you need to make sure that the IRB has maintained quorum and that if it takes a vote that that vote is a valid vote. Because I will tell you, the auditor who is coming behind you and looking at your meeting minutes is looking at that exact thing. They're tracking who came, who went, how many members were present, did you have approval by a majority, did you have your non-scientist? Were you able to maintain quorum before you had that vote, okay? All right.

Dr. Karen Jeans: [Unintelligible 55:01] post-meeting activities.

Soundia Duche: Oh, someone wanted to say something.

Dr. Karen Jeans: Yeah, this is Karen. I'd like to jump in to say, so Eileen, how do you keep up because you have a large IRB, a very active IRB and a lot of things going on. How do you keep up with people coming and going and try to keep up with that in terms of the meeting for purposes of trying to record minutes.

Eileen McCarthy-Dorsey: Well I'm happy to say that people don't come and go quite that often. But I sit there with my agenda and I just pay attention. If somebody gets up and leaves and I mark on that specific item that Dr. Smith left the room so I know if that Dr. Smith isn't back then they're not part of the vote. So you have to pay close attention, yeah. You really do for\_

Dr. Molly Klote: And Eileen, hey this is Dr. Klote. Do you then actually record that in the minutes, that he left the meeting at what time and when he came back in? Do you record that level of detail? Over.

Eileen McCarthy-Dorsey: If that individual does not come back, yes, a statement will go in that Dr. Smith recused from the motion to vote or was excused or abstained, whatever it was. And if they come back in, I don't necessarily put the time, I will say that. But I do keep track of if they come and go. Yes. Over.

Dr. Molly Klote: Yeah, thank you. So yeah that's something to consider is that if somebody steps out for a lot of the discussion, and then they just happen to come back in right before the vote, they may want to abstain from voting on that item. Over.

Eileen McCarthy-Dorsey: Yes. And that has happened to me where that member has abstained and we put that in the minutes that say abstained because they were not part of the discussion. Over.

Soundia Duche: Thank you all. Great clarification there. All right, so now we finished our meeting. We're ready to write our meeting minutes. What has to be included in the meeting minutes? What must be included? According to the Common Rule, the meeting minutes have to include information on attendance at the meetings, okay? So attendance of everybody. Voting, non-voting, guests, alternates. Action taken by the IRB. Remember we talked about the motions that the IRB made. The votes on these actions including the number of members voting for, against and abstaining; we've talked at length about all of those. The basis for requiring changes in or disapproving research. Modifications that you require or the rational for why you have to disapprove a study. And a written summary of the discussion of controverted issues and their resolution. We talked a little bit earlier about controverted issues. This is what the Common Rule says has to be, must be included in the meeting minutes, okay?

In addition to what the Common Rule says, VHA Directive 1200.05 adopts those same requirements but also adds two additional requirements in terms of what must be included in the IRB minutes. That the IRB determined that all the criteria for approval of the research are satisfied. A statement to that effect. And documentation that all criteria for a waiver or alteration of informed consent or documentation of informed consent have been met if applicable. So, this begs the question, surely that's not it right? And the reality is no, that's not it. But in terms of what the regulations say, that is the minimum. That is the minimum. What you must remember though, remember those two pages that I really didn't focus on all that much of required determinations the IRB has to make? The IRB still has to make those determinations. And unless it's documented somewhere, the determination wasn't made. What the regulations say is, the documentation of the specific things that have to be in the minutes are limited to what we just went over. However, you can include more and many people do because it makes a lot of sense to include certain additional things like the [unintelligible 59:45] determination for example of the study, in the minutes. It's an easy place to be able to find everything as opposed to having to go to this reviewer form. This approval letter. As opposed to having to compile all these different places where you include disparate information to show the trail that yes, I did make all the determinations, here's you know numerous different places.

Again, your local VA SOPs and your IRB SOPs may be more robust with respect to what you include in your minutes. You're always held to what you state in your SOPs. So in addition to what the regulations state, if you say that you will include certain things in your minutes, you have to include them in your minutes. When you're audited, the auditor is going to look to see what you have in your minutes based on what your SOP is saying. Additional IRB required determinations, there are certain best practices that say certain things should be in the meeting minutes versus other sources, but again your SOPs will dictate a lot of that. Reviewer forms, as Eileen mentioned they use, as the VA Central IRB use, can provide supporting documentation of specific determinations made by the IRB. Approval notices can also provide that documentation. And so it's not just about the minimum. That's the key.

Dr. Karen Jeans: So this is Karen .

Soundia Duche: Karen, go ahead.

Dr. Karen Jeans: Okay, so can you go back to the last slide?

Soundia Duche: Yep, sure.

Dr. Karen Jeans: So I would like to ask Dr. Borror to comment in terms of if [unintelligible 1:01:18] this call about, in terms of ORO, is there any advice that Dr. Borrer has speaking on behalf of ORO of issues they see in the minutes, especially when they're looking at SOPs. And this slide of going beyond the regulatory requirements, anything that ORO has to add to this type of, this slide here about what they're seeing in practice. Or any advice for sites.

Dr. Kristina Borror: Sure. Can you hear me?

Dr. Karen Jeans: Yes.

Dr. Kristina Borror: So generally as you mentioned basically if your SOPs say you're going to do something, that certain things have to be in the minutes and they're not in the minutes when ORO is doing a compliance review, they will make a finding of non-compliance because you basically, if you say you're going to do it in your SOPs, you have to do it. So as was stated, you make sure that your SOPs state stuff that you really are going to do.

Dr. Karen Jeans: Thank you Kristina.

Soundia Duche: Thanks Dr. Borror. All right. There is a meeting minutes template. I'm not going to pull it up, but it's in your handouts. This is again, just one tool. If anybody has other templates, send them to me. I don't only want to keep using VA Central IRB meeting minutes templates. I'm happy to share other great tools, but you've got to send them to me. But so this is a tool. You have it in your handouts and it just shows you an example of how they lay out their meeting minutes. And so to the extent you find it helpful, use it or tweak it.

So once you have your IRB meeting minutes, they have to be circulated right? VHA Directive 1200.05 says that a copy of the final IRB minutes must be submitted to the R&D committee in accordance with local SOPs. If the IRB of record for a VA facility is the IRB of a non-VA entity, then there's two options okay? The non-VA entity either has to provide VA with or access to unredacted copies of the meeting minutes in a timely manner that allows the R&D committee to review the minutes. Or they have to provide VA with access to redacted copies of the meeting minutes in a timely manner so that they can be sent to the R&D committee to review. And they have to be willing to allow relevant VA personnel to review the unredacted meeting minutes within two business days of receiving a written request from the VA. And I would think normally that's also stipulated in the MOU as well, but it's part of our policy and they should agree in their MOU to follow our policy. Karen, do you want to add anything to this?

Dr. Karen Jeans: [Unintelligible 1:04:20] but I think coming up there's a slide, but we really don't have a problem with [inaudible 1:04:24] stated, we do [inaudible 1:04:25] as a part of our MOU and so whatever we put in the MOU is what we bind when we're using a non-VA IRB or we're using another IRB, you know the NCI or all of us or your academic affiliate. And so this is a required component of the memorandums of understanding that we [unintelligible 1:04:44].

Soundia Duche: Okay, perfect. All right. IRB letters and notifications. Just going to ask Eileen to comment on, do you have any tricks or things you've learned to make the process more efficient Eileen, when you're preparing your letters and notifications.

Eileen McCarthy-Dorsey: Well I will say this, I love templates and I love copying and pasting. Best thing in the entire world to be able to copy and paste. However, we still use MIRB, so again we're lucky. MIRB may not be the greatest database out there, but we do not have to create a lot of our letters, approval letters, notifications, our minutes, our agenda. We input the information into MIRB and it spits everything out for us. The only letter that we do manually is our ACOS notification for initial reviews and continuing reviews. My minutes, the only difference is, I draft all my minutes as a Word document. I then send that Word document to my chair. He makes changes as track changes, we love track changes around here, and when he sends it back, the Word document to me, I then finalize it and put it into MIRB and spit the minutes out.

Soundia Duche: All right. So the last thing I'm going to say, and I'm just going to spend, I really only need to say one or two sentences about this. Common challenges and struggles. If you're finding that right now you're struggling with any of these things, lots of items require return to the convened IRB after initial review, protocols have to be reviewed multiple times. Your meeting minutes are too long, you have pages and pages of required modifications and it's taking a very long time to prepare the meeting, two things might be at play. One, most importantly, is that study ready to be reviewed by the convened IRB? Because if you submit a study to the board that is not clear, there's missing information, they haven't sent correct documentation, you're going to have deferrals of that protocol. You're going to be creating more work for your IRB as well as for you, the administrator and managers who have to write these long meeting minutes. So really investigate if that's the case. And then the second thing you might want to look at is, are you including more information than necessary in your meeting minutes? Could you take advantage of using reviewer forms? Maybe you're not using your reviewer forms and you need to. Maybe your checklist needs to be a bit more thorough. So just things to think about. And so with that, we're going to move on to questions so that we can have some time for questions. I have Dr. Borror, I have Dr. Jeans, I have Dr. Klote and myself, and Eileen. So Erica, if you can go start the questions and whoever wants to respond, just chime in. I know we're all remote, but we'll do our best to coordinate the responses.

[Pause 1:08:02-1:08:21]

Dr. Karen Jeans :This is Karen. While we're waiting for the questions, I do have one that didn't get addressed, that I'd like to bring up. I'd like Eileen to address this one. So in terms of how you finalize your IRB minutes, what is the process you use Eileen? Eileen?

Eileen McCarthy-Dorsey: Say that one more time, I'm sorry.

Dr. Karen Jeans: The process that you've used to finalize minutes. What is the process that you use to finalize the official set of minutes?

Eileen McCarthy-Dorsey: Oh, the official set of minutes. Once I do it as a Word document and the chair reviews it and he and I are satisfied with the final Word version, I put it into MIRB. MIRB will create the minutes for us and send it to the chair. He signs it and our minutes are done.

Dr. Karen Jeans: Okay.

Eileen McCarthy-Dorsey: Having a database that will populate all of the information that we need in all of the correct spaces is phenomenal. Again, I don't work for MIRB, but I will say it's a fairly decent database. So you know, for that type, for it to populate. You put the information in, it just populates all the way through. If you put it in for the agenda, it will take it from the agenda to the minutes. I'm a Word person so I like to type everything in Word because of track changes and it just makes it easier and then just dump it into the database.

Dr. Karen Jeans: Thank you Eileen. I call you Eileen [unintelligible 1:10: 05] all the time so thank you.

Erica: Okay I'm ready with two questions. The first one, your example raises technical questions as to when does the roster change. If the person quits what other technicalities have to be made to remove them as members?

Unspecified speaker: Eileen, why don't you take that one?

Eileen McCarthy-Dorsey: Me? Okay. Well we've never had a member quit on the spot, so that's always good thing, but what we do is we amend our roster with [unintelligible 1:10:54]. We still doing that. And we update our roster in our database. But other than that there's nothing. We don't do anything. We do nothing else.

Unspecified speaker: So Kristina, what would you expect to have happen as ORO?

Dr. Kristina Borror: So currently we do require that to happen through ORO. So if you have any changes to your roster you do need to go through us and give us, you can start the submission process online with the electronic submission system at OHRP, but don't actually submit it, send us your submission number and the password and then we'll go online and take a look and make sure everything is okay. We'll want to look and see your printout of your physical roster and tell us whatever the changes are. And then if everything is in order we will tell you to go ahead and submit it.

Dr. Karen Jeans: And Kristina, this is Karen. And so until they hear back from ORO that it is acceptable to submit the roster to OHRP, the roster is not considered to be revised or changed yet. Is that correct?

Dr. Kristina Borror: Yeah. So I mean you are supposed to maintain an accurate roster. I guess there is some discussion about whether that's the roster on site or whether that's the roster that OHRP has, especially considering that the current Common Rule does not require that to be updated. But the current 1058.03 does require that those roster changes be reported to ORO and that you go through ORO to get that update.

Eileen McCarthy-Dorsey: Can I add something to my statement?

Unidentified speaker: Yes.

Eileen McCarthy-Dorsey: I completely forgot about that. Whenever we make changes, we always go through Priscilla. Everything goes through Priscilla, she says yay or nay and then it's done. However, when we make the changes, so if a member leaves and we're in the process of making that change, I've never counted that person towards quorum. I mean, how can we include someone in quorum if they don't want to be bothered with the IRB.

Unidentified speaker: I just want to add that Priscilla is one of the people at ORO that reviews those. We have a fairly new email address for any roster changes or updates to your FWA and it's OROFWA@va.gov.

Soundia Duche: Oh Eileen, I think to get back to your question is that you know, if they're still on the roster, then your quorum doesn't change, but who shows up to the meeting. Of course that person isn't going to show up to the meeting anymore. But I think until the change is official, you're going to have to count them as a member and therefore they are going to in fact affect your quorum. Correct me if I'm wrong Kristina.

Dr. Kristina Borror: That sounds right.

Eileen McCarthy-Dorsey: Okay. That's something new for me. Thank you.

Erica: Okay, next question. If you record the meeting, is it now an official record that can be audited?

Soundia Duche: I'll take that question and ask Karen to chime in because we actually covered that before. Think of the recording as your handwritten notes. When you're writing your handwritten notes these are temporary records that will result in the final meeting minutes. So similarly your recording is being used to assist you in the preparation of the final meeting minutes. Karen, do you want to add to that?

Dr. Karen Jeans: Yes, I would. Thank you. So in terms of whether or not the audio recording is an official federal record that comes under the record control schedule. The answer is no, if, and here's the big if, you transcribe it or you take notes from it to create another document. That's how it works. They may fall under the general schedule to [unintelligible 1:15:39] they can be destroyed because they are considered to be a working document. It's a document you use for your work in order to create an official record, the minutes, or an official transcription if that's the way your minutes are done. And there are some IRBs across the country, and I'm not talking about VA, where the minutes are the actual transcription of the recorder which is not something ORD would recommend. But that's how the recording works in terms of whether or not it's an official record. Not so if you transcribe it or you're using it to create another document. Thank you.

Erica: Next question. My IRB members who are conducting studies by the same sponsor recuse themselves. Is this correct?

Dr. Molly Klote: So I think what we're trying to get to here. This is Dr. Klote, is that, I think the question means that if the member is also sponsored by the same company and they're asked to review another study by that same company, there could potentially be a perceived conflict of interest. And if it's perceived it's probably real. So just to protect your institution, it probably would be best to have someone else review that study. Anybody else on that one? Over.

Dr. Karen Jeans: This is Karen. I'll jump in on this one as well. It's a very fascinating question because some of the sponsors are [unintelligible 1:17:25] industry, they do a wide range of pharmaceutical products. And so you know it's one of those, there's not a hard and fast rule. It's like what Dr. Klote was saying. Is there a perception of a conflict or not? It truly does depend upon the situation. So it is about whether or not there is a perception. So there is not a hard and fast yes or no on this. It's going to depend upon the relationship between the investigator and the sponsor and the potential of whether or not the investigator, excuse me, the member would be conflicted, or could have perceived conflict of interest when reviewing other studies that are being sponsored by that entity. Thank you.

Erica: Okay Karen, it's 1:28. We have time for one more question?

Dr. Karen Jeans: Yes.

Erica: What is the difference from the previous question that requires the majority of the roster, oh I think that's regarding case study number two. Does anybody? Can\_

Soundia Duche: Let me try to pull that up. Can you go on to the next question, we can come\_

Erica: Sure. So things can be included in the minutes that are not specifically mentioned in the SOP?

Unidentified speaker: Eileen would you take that one?

Eileen McCarthy-Dorsey: We're probably going to say the same thing. I'm going to say yes. You know, if something is discussed at a meeting and the chair or a member feels that it's important enough to be in the minutes, it should go in the minutes.

Dr. Molly Klote: Yeah this is Dr. Klote. I don't think there's any way to anticipate in your SOP every possible situation that's going to come up and everything that you could possibly document. But what is important is that you set a standard within your local SOP for what you want that standard to be for the recording of your minutes that absolutely incorporate those minimally required elements and then those things that help you as an institution and make you feel comfortable that you've captured everything you want to capture to document. Over.

Soundia Duche: Erica, if you can go back to that last question. I have the case up.

Erika: Okay. What is the difference from the previous question that required the majority of the roster?

Soundia Duche: So the question is asking, case study two. That was the one where remember we had a board that was operating at quorum. Quorum was five, they had five members present at the meeting. And the scientist decided he was done, he wanted to leave the IRB and he left. And our question was, has the number of members required for quorum changed for the remainder of the meeting. The answer was no. And yes, there is no difference between that and just the calculation of the number of members required for quorum. The key that we're trying to illustrate there was that quorum is based on your roster. And so quorum is calculated based on the majority of voting members on your roster to include a non-scientist. And so the amount needed, number of members needed for quorum for a particular IRB will be based on the roster and that number will not change until the roster changes. What does change is whether you can achieve quorum. Whether throughout the meeting you have at least the minimum. And you can fall below the minimum at any point. If you lose your non-scientist or if you lose a member and you're operating right at the minimum number. Okay? So we tried to phrase it in different ways really just to illustrate the point that the number for quorum is based on the roster, your ability to achieve quorum changes. But for your roster you have a set, specified quorum until you change the roster. So I think that is it. We thank you all for attending. Sorry for the late start, but it was wonderful having Eileen on and so it was well worth the wait. Thank you Eileen. We appreciate the insight and feedback you gave. For those questions we weren't able to get to, I will go through them and we'll try to get you answers, fear not. Thank you Dr. Klote, Dr. Jeans, and Dr. Borror, thank you. And Erica, thank you for a seamless meeting. Really appreciate everyone's time. Have a wonderful weekend everybody.

[ END OF AUDIO ]