Regulation Audio Transcript

Pete Seidenberg: Welcome, and thank you for joining us for the Family Medicine Department Chair's Research Curriculum. Today's session is on lessons learned navigating regulations and compliance. To help you increase family medicine research in your department.

Pete Seidenberg: I am Dr. Peter Seidenberg, I am the chair of family medicine at LSU Health Shreveport School of Medicine, and I'm also the chair of ADFM's Research Development Committee.I'm going to ask our distinguished panel to introduce themselves as well. Toshi.

Tochi Iroku-Malize: Hi, I'm Tochi Irokimaliz. I am a professor and chair of family medicine at the Zucker School of Medicine, located in New York.

Pete Seidenberg: Excellent. And Rochelle.

Richelle Koopman: Hi, I'm Rachelle Koopman, I'm chair at the University of Missouri and past president of NAPCRG.

Pete Seidenberg: Excellent. And thank you both again for joining our panel today.

Pete Seidenberg: So, our panel is composed of chairs representing departments with history of low, medium, and high research productivity. I'm representing the low research productivity department, Toshi is the medium, and Rochelle is the high. However, we all have experience in departments with different levels of research, so we're just going to share our experience and hopefully some things that have made us successful in some of our departments in the past and currently.

Pete Seidenberg : Um, so, the first question…that I have is…on what types of training are required for all personnel involved in research projects. Toshi, do you want to take that one?

Tochi Iroku-Malize: Uh, sure. So, when it comes to the… first of all, HIPAA. Let's start with the basics, right? So, no matter what level you are, everybody should know about handling patient health information, because you're likely to use that in research, so how to… just knowing that. Um, but really, for research purposes, the human subjects research, uh, city training. So that helps you to understand about how to interact with people, how to use their data, just understanding, you know, based on history, what has happened in the past, the inappropriate use of information, and getting kind of sent, and things like that. And then, of course, that whole responsible conduct of research, and that's really, really important, just ethically, as well as, you know, in terms of federal funding and other things like that. And then, of course, conflict of interest. You… all… anybody who's worked doing research needs to have put out that conflict of interest information just ethically, in terms of compliance and other… other things.

Richelle Koopman: And I'd add that if you're doing a clinical trial, you generally have to do

additional, uh. Good clinical practice training, additional modules, yeah. On top of your other IRB.

Pete Seidenberg : Yes, and those modules don't last forever, as far as.

Tochi Iroku-Malize: No.

Pete Seidenberg : You have to repeat them, um, every so often, every couple of years, it seems, and so you have to make sure that you're up-to-date on your training, um. Otherwise, uh, your IRB protocols won't be accepted, and. Um, and it all makes sense. It's all, as Toshi said, all about. Being ethical in research. Um, then there's… there's also, um, if you're doing any kind of animal research, that has a whole separate training, and so I had to do all of that in some of my concussion research. And so, um, so there's… there's…animal research subjects training as well. It's not called that, but, um, and so…Uh, so those are different things. So, um, Rochelle, how do you communicate with your faculty. About the need to…to do their compliance training and their IRB uh, training.

Richelle Koopman: Right. I think one thing that's important to communicate is that, um. You can't really do anything in a research project except planning. Uh, uh, before getting IRB approval. You, um…you can do some feasibility things, like…Um, uh…Do you think it would be appropriate to, um, recruit. Uh, you know, participants in this way from your organization. You can… you can say something general like that, but you… you cannot contact. Or make arrangements to contact any… or get lists. Uh, for any type of participant, uh, until you have IRB approval. Now, there are some…some pre… uh… you actually can…Uh, do some preparatory to research work. Uh, but it's still good to talk to the IRB about that. Just getting to know, like, numbers of people that might have a certain condition. Queries like that can be…can be done, but, um, it's best to communicate with the IRB about that. Um, another thing that I like to…let, um, faculty and especially trainees know, is that everyone who's involved with the research needs to, like, anyone who's going to touch the data needs to… needs to be approved. Uh, there's sometimes… it's sometimes complicated if you have to go across institutions. Although there's an organization called CITI, that, um, often. institutions use, and so, uh, you can… you can show them your… your city. Uh, certification from… from a different institution. Um, the other thing that I like to communicate to people is that it takes a lot of time to complete the modules, um, especially, uh, the, the clinical trials modules. But even so, the, the, um, the… the…baseline, uh, IRB, uh, human… human participants protections modules. They take a while to, uh to complete, especially if it's your first time. And you do need to ensure that everyone on the project stays, um…certified throughout the length of the… of the project. Luckily, the IRB now notifies you of that, like, if someone's training is running out, and um… and you can take appropriate measures, so… I think those are the big things that I like faculty and trainees to know about… about IRB. And research the initial things.

Pete Seidenberg: Yeah. I, I think…

Tochi Iroku-Malize: And I'm gonna just say that. It's important… everything that was just mentioned is really important, because you have to stay… throughout the entire project, it's not just in the beginning you say, okay um, we've done this, you're going to do this, and we bless you, go forth and do your project. You have to continue having that communication with them, because the… first of all, faculty change, right? See? I mean, there are times where faculty may move on to other roles, or they may move out of the organization, and so that changes. You want to proactively identify issues that you're going to need to.

Pete Seidenberg: Right.

Tochi Iroku-Malize: deal with before the IRB gets to you. You want to guide them and support them as they're, you know, having the regular… having meetings with them regularly to say, okay, how are things going? What do you need? And it also helps to foster that culture of compliance so that they say, okay, what regulations have changed that we need to be on top of? What do we need to do? Um, it helps to also streamline that process, because not only do faculty change, but systems and departments change. Rules that govern the department may change. The sponsoring institution, things may change, and so how do we make sure everything is aligned? So keeping that open line of communication is helpful so that everybody's on the same page.

Pete Seidenberg : Right.

Tochi Iroku-Malize: And it also ensures accountability, because if they know a meeting's coming up where we're going to have a conversation, everybody's going to kind of like, okay, where am I, what am I doing? Okay, and then everybody's accountable, because you as chair are going to be accountable, because you're signing off on these, right? Um, so you need to know, because there's nothing worse than a chair being called in by the IRB to say, hey, what's going on?

Pete Seidenberg: Right.

Tochi Iroku-Malize: So, uh, you know, so this helps everybody to remain accountable.

Pete Seidenberg: Yeah, you have to sign off on every IRB submission.

Tochi Iroku-Malize: every IRB submission and revision, and every… yeah.

Pete Seidenberg : Yeah and they come… they come after you, so…

Tochi Iroku-Malize: Oh, yeah.

Pete Seidenberg: So… so be in the know. That sounds a little… little scary. It's not really that scary.
Tochi Iroku-Malize: It's not that scary, but it's just so that you know, it's just like you're

responsible for the members of your department, right? So, even clinically and academically, so, yeah.

Pete Seidenberg: Right.

Richelle Koopman: I also advise people that if they've never done this before, work with at least someone who has.

Tochi Iroku-Malize: Yeah.

Richelle Koopman: Um, yeah, a bunch of people working together, and none of them have ever done an IRB application is probably not a great idea. Get advice from someone who's done it before. Yeah, it's not so very hard, but you should do… there's… there's…

Pete Seidenberg : Yeah, so that brings…

Richelle Koopman: There's ways to do it right, and ways to do it wrong, yeah.

Pete Seidenberg : Yeah, so that, that brings, uh…the question of how do you learn to do it right?

Pete Seidenberg : Um, and so, do you… have you established a point person. Uh, who's your insider on the IRB, who can help you with questions.

Tochi Iroku-Malize: Oh, okay, I guess I'll take that one. So how I learned to do it right…Was first going through the CITI training, right?

Pete Seidenberg : Right.

Tochi Iroku-Malize: And then signing up to be on an IRB committee. So I am on the IRB, because there's nothing… yeah, so I am on an IRB. I have been on the IRB for almost 15 years now, um, and they moved me to… because I don't get to review my own, because we're a big institution, so, uh, we… they split it up, and so all… anything that's coming from Department of Family Medicine goes to the other IRB group. I take… I handle the other ones. So, yeah, so that was the first thing. At first, I learned… did my city training, and then I jumped on… became a member of the IRB and that is the best way to know what's going on. So, uh, but you don't have to do that. Again, reach out to someone else who's on it. I think finding out who's on the IRB… because the IRB liaison for your, or the IRB staff. They don't… they want you to succeed the first go-round. They don't want to have a meeting where they're tearing apart your submission and saying, oh my gosh, oh my gosh, oh my gosh. So the staff.

Pete Seidenberg : Okay.

Tochi Iroku-Malize: Because, honestly, because they don't want it to come back. I'm speaking

from experience. They don't want your submission to go and come back and go and come back. It's like, oh, this one again. So, um…reach out to the IRB staff. There's somebody there that will say, here, these are the guidelines, this is how we're doing it, to get the, you know, to know how to do this.Um, and then they will give you personal guidance on this. Uh, that helps. The liaison is really, really helpful. Um, they're going to help with the pre-submission review. And then if you do get… if you submit it and it gets sent back to you, it's okay. Sometimes… some of the things are just minimal, some things are big… bigger, but then that's a learning experience in itself, right?

Pete Seidenberg: Right.

Tochi Iroku-Malize: My teams, till this day, some things still get sent back, because I don't always fully review before it goes… gets sent and then it bounces back, but that's okay. You say, okay, what are your issues? And then work on it. So, that clarifies the requirements for the study, and maybe they'll give you some insight. Maybe your question was not really the right question, you know? So, um, and then, you know, and that also helps to reduce the stress and frustration that you're going to have later on, and it helps to avoid, um, some common pitfalls that a lot of us reach out to the people that are on the IRB that you're going to submit to, if they have a staff member that helps you, the liaison, and if you have somebody on your team that's willing to apply and be on a committee for, you know, just to try it out for a year or two, that's also helpful.

Pete Seidenberg: You know, and that's… and that's actually a great thing for promotion, for one of your faculty members to be on the IRB.

Tochi Iroku-Malize: Oh, yeah. Yeah.

Pete Seidenberg : You know, one of the lessons I learned. Was not to be offended when it's sent back.

Tochi Iroku-Malize: Yes.

Pete Seidenberg: Right? And so, they're… they're doing their job, they're actually trying to help you. And, um…And being on the IRB, you… you would… you learn their perspective. Um, and so I think that's, uh, very valuable advice.

Richelle Koopman: Although, although, a caveat.

Pete Seidenberg : Um…

Richelle Koopman: I don't often advise people to be on the IRB, because the admissions committee and the IRB committee are, I think, the two committees at our institution that take the most time.

Pete Seidenberg: They do.

Richelle Koopman: And… and I… I don't want, like, a junior investigator being…Like, having their time, like, completely sucked up before they, you know, establish themselves and get funding, yeah.

Pete Seidenberg: That's a good point.

Richelle Koopman: So, yeah, uh, there… but I, I think…Um, working with someone who's… who has experience, and… and definitely. You know, if you have a question about. How to do something? Rather than submitting the application, just call them. Um, and explain, here's what I'm struggling with. Um, and, you know, talk through it, and they'll tell you the right way to do it the first time. Um, and that avoids a lot of back and forth. And for certain types of applications, the IRB only meets. Periodically, and so then that can set you back a number of weeks if you miss it the first time. It's not a big deal if you miss it, if you're… if you don't have a big time constraint, but if you do, then… then it's a little bit…it makes things a little bit harder. And some things… some… some things that they return for you. Uh, you can just answer, and some things…We'll require you to answer, and then they re-review. So, um, yeah, just calling someone there, uh, can really help, and they're normally really helpful, because they, as Pete said, they do want you to succeed, and we're really all working together as a team. To ensure protection of the participants.

Tochi Iroku-Malize: And you mentioned something real quick. Sometimes when you submit it, before the meeting, they may… because the reviewer is going to look it over and ask questions. Answer those questions, because if you answer the questions, then that will alleviate the problem when they get to the meeting, as opposed to them saying, oh, why did they do this? Why did they do that? Well, we reached out to them, and they told us this, this, this, this, this, and so that's helpful. So answer the questions. If they reach out to you after you've submitted before the meeting, please respond to them.

Pete Seidenberg: So… so I think that's really important to share with our…Uh, faculty, right? Um, because we're not necessarily on every protocol. But if…our faculty's not answering the questions, they're never going to get through the IRB, and they're just going to frustrate the IRB and just make it harder on themselves. So, I… I advise them to look for questions and emails from the IRB, and to…Not let those sit to, to try to answer them quickly because otherwise, it just delays everything and it is part of the learning process. Um, is… is everyone, Toshi, in your department trained in how to submit an IRB, or is it only certain people?

Tochi Iroku-Malize: Um, it's… so it's a… it's… all residents have to do it, have to go through city… the city process, right? All faculty, everybody has to do that.

Pete Seidenberg : Right.

Tochi Iroku-Malize: Um, not everyone knows exactly how to do it, but we do have someone in our… on our team who is in charge of research, because I don't have a full research department, I have a research person, right? And so that's her role, and that's not how she started. She started out doing something else, and it was like, tag, you're it, because I needed that. And she's grown in that role. And so, uh, so she's the one that's, you know, kind of the liaison to… for our department to make sure people's, uh. Right.

Tochi Iroku-Malize: IRBs are in the right order. Um, but yeah, so they… not everyone, so the answer is no, everyone is not trained in it. However, I have one person who is definitely trained, but all residents, faculty, etc. They have to do city training.

Richelle Koopman: Mine don't. Um, yeah, I… not everyone uh, does city training. Um, there… if people are not actively doing research, then they haven't done it. So I would say probably about half of our faculty. Um, have done CITI training and some of our residents.

Pete Seidenberg : Yeah, so, um…It's similar in my department. The people who are 100% clinical, not involved in education, they're not core faculty, they're not mentoring medical students in research in our department, uh, don't necessarily have to do it, but I encourage everyone to do it. Um, and I actually monitor. During their annual review, where they are in their trainings. Um, you know, when it's due, so that they're not surprised if. They are doing research, um, but all of our residents have to do it, like… like you, Toshi. All of our core faculty have to do it as well, because I require the residents to bring a faculty along with them. And so, um…So that's been… that's been helpful, but I do have…People who are experienced in IRB submissions who help, and they're not necessarily clinicians, some of them are, but they're not necessarily clinicians. And so basically, people who can facilitate. Um, and make it easier for our clinical researchers, especially people who… their main job's not research.

Tochi Iroku-Malize: And I'm going to clarify when I say faculty, I mean academic faculty.

Pete Seidenberg : Yeah.

Tochi Iroku-Malize: Not my clinic… not my pure community-based clinicians. Academic faculty, all right.

Pete Seidenberg : Correct. Yeah, we're… I think we're all doing the same thing.

Pete Seidenberg : So, how about consent? Are there… are there rules around consent that…Um, are specific to your institution. Um, how'd you learn about that? Uh, Rochelle, you want to tackle that one first?

Richelle Koopman: Um, yeah, there are rules about consent. Obviously, you have to be on the IRB to uh, uh, uh, to get… to… on the IRB application to obtain consent Uh, uh, which, you

know, some people think, like, oh, well, the nurse in the clinic can get consent. Not unless she's on your study, uh, not unless… plus, like, she probably has other jobs to do, so, like, not a great plan.

Pete Seidenberg : Right.

Richelle Koopman: Uh, and on our IRB, um, applications. We have to, um…designate who is authorized to obtain consent. So that's like a… like a subset of your… of your… of your people on the IRB, uh, application on your study. Uh, you have to be designated to… able to obtain consent. I think the thing about consent is, um. Uh, that it is…Ensuring that the participant. Has an understanding of what's… what's going to be happening and to… and that they, um…and that they, you know, willingly. Uh, and without coercion. Uh, would like to participate in the research. Uh, and so it's up to you to ensure that they have that understanding. And that they are…consenting of their own free will without coercion. Um, there are different levels of studies. Um, have different…requirements for consent, so…Right, sometimes…you can have a… a waiver of consent. Sometimes you can have a waiver of documentation of consent. Uh, which is not the same as a waiver of consent. Waivers of consent are much less common and then, you know, full…Informed consent with a signed document that you must keep on file. Uh, the other thing that's important about consent is that you must…Be sure that the participant knows how to contact.Someone involved with the study, usually the PI, if they have questions or something goes wrong. Um, so that's an important part of consent as well. Um, some things with…Uh, waivers of consent might be some very low… Um, risk surveys, because taking the survey is an implied form of consent.Um, you still have to…Uh, document that you've…obtained IRB approval to… to… to give the survey. Um, sometimes if you're, like, doing an interview or something that's not…Deemed to be very risky.You can have a waiver of documentation of consent, which is basically that you give.the participant a piece of paper that says some things about the study. It's usually only one page, and they don't have to sign anything. And then, for more involved studies. Uh, um, the full consent form, usually multiple pages with signature lines. Uh, for the person giving and obtaining consent. Um, another thing…That's important is that you do have to keep those documents.

Pete Seidenberg : For a long time.

Richelle Koopman: full consent, and usually the IRB has templates, uh, because they have preferred language.

Pete Seidenberg : Correct.

Richelle Koopman: And the language must be. Um, at usually a less than 8th grade, like, uh, reading level, so that, that, that it can be accessible to the widest possible amount of people. Um, it may need to be in different languages, and all those consent forms have to be reviewed by the IRB, and you must have your consent form on file, and it must be the most recent approved consent. Um, you must always be using the approved consent form, um, when

you're… when you're… when you're doing that.

Pete Seidenberg : Excellent.

Tochi Iroku-Malize: I'm going to add, at our institution, we also have the protected population, right, in terms of that and for us, protected population includes. Because we were a health system before we had the school. It includes the residents. The students, the employees.Of the organization. So we can't just give our residents and students and nurses surveys just like that, because technically. They are under undue influence because it's their employer who's doing the survey, so it's not technically voluntary.

Pete Seidenberg : Right.

Tochi Iroku-Malize: So, because that's a… so, if you have to give a survey, you have to get… they have to… they have to be able to opt out. So, you have to state that this is a protected population. That we're giving this survey to. Even if you're asking this… their opinion of something clinical that's happening, because you may want to get two parts of it, you want the patient's perspective, and they want the physician, or the resident's or student's perspective. That's… those are two consent forms. Uh, so you… one for them, for the students, the members of our organization, and then one for the patients, because they're… this is also something that, you know, so that's a… something to think about. Um, and then, of course, capacity to consent. That's, you know, are they legally and mentally capable of informed consent? And then again, you mentioned the languages, we definitely put those in. They have to be submitted to the IRB. The one that you're giving, what population are you giving? What language are you using? If you're using… if you're using multiple languages, Queens, we live… I live in New York, Queens is very… has so many languages, so just, what are you going to use for that? Um, and then just making sure everybody has that information, and then compensation. Is there compensate… compensation has to be put into the consent form to say, are you being… are they being compensated for um, participating in the study, how much, etc, because that could also be a coercion in some state… some way or form and will they be compensated for any injury that results from them? Um, participating in the study to be frank up front, and say yes or no, are you going to be compensated should you have injury, or where should you… where do you go to if you do have injury from participating in the study? Um, and so, um, and then the opportunity to ask questions. It has to be there. Did you have an opportunity to ask questions? And, um, and yeah, so… and that's the whole thing, that you have… you have the opportunity to ask questions of the individual who's getting the survey, um, getting the consent from you, so…

Richelle Koopman: Yeah, doubling down on that, I mean, vulnerable populations are… are… you have to take extra care, and… most people don't realize that student… well, they may realize about the students, but our employees. Our vulnerable populations, because they…You, again, to protect from undue influence. And that's a common mistake that people will…give surveys to…Um, patient participants, and then they'll also give it to. Physicians or nurses, and

not realize those… their…You know, protected participants also, and even maybe a little bit more so. Um, and then children have, have special rules as well. Yeah.

Tochi Iroku-Malize: Well, that's a whole different story.

Richelle Koopman: Yeah, you have to do, um, their parents'. Um, and then you may be required to get a scent.

Tochi Iroku-Malize: Ascension.

Richelle Koopman: From the… from the child anyone who's, uh, um, incarcerated, there's lots of other protected populations that are listed in your IRB training!

Tochi Iroku-Malize: Yes.

Pete Seidenberg : Right, right. And the other, I think, important point is the consent has to say that they can withdraw consent at any point. Even if they sign up now, they can later withdraw that consent.

Tochi Iroku-Malize: Oh, yes.

Richelle Koopman: Always true. Yeah.

Pete Seidenberg : And so, um, and so, um…So, how about quality improvement? Uh, at your institution, Toshi, does QI have to go through the IRB, or is there a different process?

Tochi Iroku-Malize: So what we'll do is that we'll put the QR, and then an IRB will say. Um, expedited, expedited or not… not required. Because later on, when you want to do a presentation. Um, some… some organizations, before you are allowed to do… submit for publication or do a presentation, they want to know that you at least went through the IRB process, and they gave you a blessing, said, don't worry, you can go ahead and do this. And so, yes, so we… even our QI, we may just put it through and say, this is a quick, uh, thing, and then it doesn't even go to the meeting, its staff can quickly turn that over.

Pete Seidenberg : Yeah, and so…reaching out to find out, okay, is this an exempt QI protocol or not? I mean, I'll just call the IRB and say, what do you think?

Tochi Iroku-Malize: Correct. Yeah.

Pete Seidenberg : And no, that needs to go through the full, or yes, that's definitely exempt, please use this form. And they have a different form for, um, for the exam protocol. Are there, uh, Rochelle, are there other types of protocols that. Are sometimes exempt at your institution? Richelle Koopman: Uh, anything using de-identified, uh, secondary data, for example, a large

national data set that's publicly available, would be exempt.It's important for the exempt applications, which, as you say, are really quick and also, like, if you make changes that are…do not change the risk. They don't really want to know about it. Like, if you're going to, you know, analyze something about diabetes, and then you also want to add blood pressure. As long as it's still de-identified large data set, you're still in the exempt category. Like, it… you don't even have to tell them about it. But you do have to have it designated as exempt by the IRB. That's not a decision that you get to make, and that phone call to the IRB where they say it isn't enough either. You have to submit and have it declared exempt by the IRB, and that's usually a very short application, and it's quick.

Tochi Iroku-Malize: Correct.

Pete Seidenberg : Right.

Richelle Koopman: And, um, same for QI, um, they'll say, oh, well, this is QI, it doesn't… it doesn't need to be, but then when you go to.Um, publish, you'll be able to say that… that it was reviewed, and that's, um. If you're going to want to publish it. You're going to need to do that, so…

Pete Seidenberg : Yeah, so save that communication.

Tochi Iroku-Malize: I started to hit it that early. Yeah, do it anyway, because you'll say, oh no, I'm not going to publish, and then later on you realize, oh, I really do want to publish, so…

Richelle Koopman: Yes? Exactly.

Tochi Iroku-Malize: Yeah. So just get it done, get it done, yeah.

Pete Seidenberg : Yeah. Always, always assume it's going to be published or presented, and you're going to need that.

Pete Seidenberg : And so you're gonna need a copy of that exemption.

Tochi Iroku-Malize: Correct.

Pete Seidenberg : And so, um…keep… keep a hold of that. And plus, I, you know.what if someone accuses you of doing research that's not been approved by the IRB.You have proof that this is an exempt protocol, here's the documentation of it. Um, so, um, how about…the Clinical Trials Office. Do you have a relationship, Rochelle, with your CTO?

Richelle Koopman: Yes, um, yeah, the Clinical Trials Office.Provides additional training for clinical trials coordinators and uh… uh…Principal investigators that are doing clinical trials. Um, so it's, uh, just another…wrinkle of the IRB, essentially, yes.

Pete Seidenberg : And Toshi, how'd you learn what resources…were available through the CTO to help you with trials.

Tochi Iroku-Malize: Um, so it's interesting. Ours is… because, again, we had a health system first. Uh, but that… this actually, our clinical trials office, uh, just recently got revamped and so, luckily, I'm, I'm, um… We have our chairs meeting regularly. And we are in… the re… the head of research is in… for the entire institution. Well, we have an institute for research. But the person who's now linked to clinical, the clinical side of it, not just lab. Um, she set up a new structure. And so she has now created a way that we can, in her team, she has liaisons to the various departments. Um, so it's centralized, but then we have liaisons, and so we've been working all along all the… all this time. And so that centralized service is that single point of contact for us. Where resources are shared, because sometimes. There can be some, uh, people are in silos and applying for the same thing, and so this is a way to make sure that all of us are together in the… whatever we're applying for, because we're such a huge organization. So, they reach out to us. We have regularly scheduled meetings, uh, for all of us to be together. I have another meeting scheduled for tomorrow with my… with the person who's the liaison, uh, to find out what's going on. We get newsletters telling us what's available. Um, um, out there, so that may be specific to us. We actually have Department-specific newsletters that are sent to us about potential trials that are open, should we want to collaborate with that, and then they'll link us to other departments or other specialties both within our institution and outside our institution. So that's…Um, that's something that's kind of newer and, of course, they're going to have to help us because they've got to do the centralized services, contracts and budget negotiations, um, building compliance, regulatory support, all that, all the study initiation support, so all of these things, that's… that's… we don't have to worry about it individually, or independent individual departments. We don't even have the funding, the resources to do that, the budget to do that. So, this is all kind of new for us, because we didn't have it before. Uh, so that's… that support system and that structure. We had to…basically, come together, all the department chairs have to come together and say, listen, we want this so that it's equitable for everyone. If that hadn't happened, um, we… then I don't think I'd be able to do anything. So, uh, so that's… that's where we are at this point.

Pete Seidenberg : Yeah, so when I first became chair, one of the early meetings I had was with our clinical trials office, and… and asked to meet our… with our liaison, and basically said, what do I need to know? And, you know, what… tell me about the processes here versus…what I've done at my other institutions. Don't assume the processes are the same. I mean, some things are going to be the same, but not everything's going to be the same. There's going to be nuances with every institution and so, having that liaison and that contact to help guide you, because, again, they want us to be successful.

Tochi Iroku-Malize: Yeah.

Pete Seidenberg : They're our partners and our support, they're not our enemies, so…there…

They're here to help us, and so we need to look at it from that standpoint. Um, Richelle?

Richelle Koopman: In the area of clinical trials, we should probably talk about reliance structures.Um, like, if you're involved in a multi-site clinical trial, if you're a site. You may be requested to submit a reliance agreement. Which means that the… the primary site uh, will do the main IRB application and then a similar IRB application occurs at each of the sites, and they are Reliance sites. It used to be that you would have.

Pete Seidenberg : Right.

Richelle Koopman: different applications at every site. This was supposed to streamline things. I'm not…sure that it really saves any time, and it certainly costs money, but that's for the principal site to worry about, but if you are doing a multi-site trial, you do have to figure out who's going to be the principal site and budget appropriately for all the Reliance site fees, um, which there will be Uh, and, and, uh, that, that is a little bit extra hard, but, uh, it's for a big. Uh, multi-site clinical trial. Uh, but if you're doing one of those, then you probably…Know your way around, so…

Tochi Iroku-Malize: Right. And you've got the Office of Clinical Trials, that's their whole… that's part of their role, is to help make sure.

Pete Seidenberg : Right.

Tochi Iroku-Malize: Uh, that everything is done appropriately, because at the end of the day. This is part of their metric as well, right? So, everybody has a metric that they've got, a dashboard that they've got to, you know, maintain, so your success is their success, so…

Richelle Koopman: Right, right.

Pete Seidenberg : Yeah.

Richelle Koopman: And if you're doing a clinical trial, even if it's a… tiny clinical trial. um, you must register it with the Federal Clinical Trials Office, or you won't be able to publish it later.

Tochi Iroku-Malize: Brilliant. Correct, correct.

Richelle Koopman: Now, normally your IRB will require that, so you're not going to forget or stumble on that part.

Pete Seidenberg : That's a good point, that's a good point. Um, so do you also have an office for sponsored research?

Tochi Iroku-Malize: Yes.

Pete Seidenberg : So, why is it important to establish a connection with. That office, in addition to the clinical trials office. Um, Richelle, do you want to comment on that?

Richelle Koopman: Sure, the…the Office of Sponsored Programs that, uh, is normally the office that accepts the grant. They're actually the people who receive the funds for the grant. Uh, they make sure that, um, all of the necessary compliance. Parts are in order, everybody has a conflict of interest on file, uh, the IRB has been completed. Uh, you know, everything is…Uh, chip shape with the budget, and the funder and the investigators agree about what's going to happen. Uh, and the budget, and, um, they accept the grant, and then…Uh, they, um…generally will…Except the yearly grant, that's where you… your progress reports will go through them. The billing of the… of the funder goes through the Office of Sponsored Projects, so they're… it's… they're important in… in getting the actual money. Um, uh, so yes, it's important to have a relationship with them. And if there are any. Um, reports that are due, they'll be… they'll be tracking on that.

Tochi Iroku-Malize: But I'm going to say that they're the ones submitting the grant, right, as well, for the organization, so it's not you submitting it.

Richelle Koopman: Right.

Tochi Iroku-Malize: it has to go through them, and I'll give an example. I remember way back, way, way when I first started, there was this wonderful grant, and I was like, yay! And I started working on it, and doing everything, and just started making contact phone calls, and I got a call from the Office of Sponsors Research saying. Pause, because…We are… we are working on this already with another division and so that was the end of that. See, that was important. So I… and that was my first introduction to the Office of Sponsored Research. And then I realized, oh, and so that… that was basically how that happened, and then from that point on, learned that whenever there's something, say, reach out to them, say, this is something I'm interested in doing, and then, you know, I'm about to, you know, apply for this, and then they work with you on that. Also to note, the deadline of the grant is not the deadline of your submission to the Office of Sponsored Research. If the deadline is December 15th for the grant, you're going to give it to the Office of Sponsored Research by November 15th, so they can go through it back and forth with you and make sure it is in compliance, because that's their deadline to submit it to the… to the… the grants office… to the grantee. So, just keep that in mind. Your… the deadline is just give yourself one month earlier to give it to the Office of Sponsored Research, because that's their deadline, that's not your deadline.

Richelle Koopman: Right. Often our, you know, when we say, well, I would like to submit a proposal. Uh, to this funding mechanism, our… our grants management person will set up a timeline for us.

Tochi Iroku-Malize: Yep.

Richelle Koopman: This is the day when your budget is due. This is the day when we need full text. This is when all the letters of support are due. And frequently, there's two layers of that, right? Like, we have an Office of Medical Research at the School of Medicine that wants to check the grant before it goes to the Office of Sponsored Projects at the university. So, yes, it's a… it's a… it's a… It's not a month for us, but there is a long lead time, and you just need to know what that is so you can meet it.Um, and they help you submit a good grant that's compliant and has all the things, so that's really important.

Pete Seidenberg : And, and it's gonna be…Well, and it may also be different based upon the time of year.

Tochi Iroku-Malize: Yeah.

Pete Seidenberg : And so, if you're trying… if your grant is due December 31st. I mean, the holidays are a horrible time. Um, so your institution may have an earlier deadline for something that's going to be due over the holidays, because they're going to close their office at…

Tochi Iroku-Malize: Yes.

Pete Seidenberg : You know, such and such a time, and so…Um, so it's important.

Tochi Iroku-Malize: Because they're not clinical.

Pete Seidenberg : Right, they're not clinical. That's… great point, great point. Um…So, speaking of grants management, so what are some…Common funding limitations of grants. In your experience. Toshi, have you experienced any?

Tochi Iroku-Malize: Um…sometimes it's just in terms of the population that's served, or whether it's an educational grant, um, when they say that, no, this cannot be applied to salary, or it may not be applied to infrastructure. So there are different things that they'll say, here's the funding, but you may not use it for this.

Pete Seidenberg : Right.

Tochi Iroku-Malize: Um, and so keeping that in mind, because it depends on the grantee, who's… whoever's giving it to you, um, the grantor, I should say, grantor. So, um, keeping that in mind, that paying attention to that, and that's where your office, uh, you know, that the Office of Grant Support helps to tell you, okay, you can't ask for this, because sometimes you'll say, oh, I got denied this, I'm going to use this and apply it at this other grant. No, not necessarily so. Indirect costs, direct costs, things like that, so…knowing what you are and are not allowed to spend that money on is very important, especially as you prepare your budget. Because you don't want to kick back, or ignored, right? They may say, oh, they didn't pay attention.

Pete Seidenberg : Yeah.

Tochi Iroku-Malize: And that's tossed out.

Richelle Koopman: Food is always a thing. Um, yeah, it's, uh… there was a time when you were not allowed to pay for food at all.

Tochi Iroku-Malize: Yeah.

Richelle Koopman: Uh, and now you can sometimes pay for food, depending on the circumstances. Like, if you're running a focus group, like, you might be able, like, after work, you might be able to pay for food, but you might not. Um, you have… that's something to check. Some have restrictions on, like, whether or not you can pay for travel to present. Um, uh, and internal grants typically don't…support investigator salary. Um, they don't allow that, although you can…Um, support salary of a… of a research assistant. Frequently on an internal grant.

Pete Seidenberg : That reminds me of something called. cap gaps. Richelle, are you familiar with that term?

Pete Seidenberg : Can you educate?

Richelle Koopman: Oh, you mean the NIH cap?

Pete Seidenberg : Yeah.

Tochi Iroku-Malize: Right. That's the salary cap.

Richelle Koopman: Yeah. Yeah.

Pete Seidenberg : And so that… that salary cap that the NIH allows. Is not the same…for percent effort. As what your faculty's salary is.

Tochi Iroku-Malize: Right.

Pete Seidenberg : So, so 10% NIH effort.

Pete Seidenberg : Versus 10% effort in your institution.

Pete Seidenberg : Are… those are often two different numbers.

Tochi Iroku-Malize: Right.
Pete Seidenberg : As far as the dollars.

Richelle Koopman: Right.

Pete Seidenberg : So, so how do you…Richelle, in your department, how do you make up that difference?

Richelle Koopman: Right, yeah, so, um, as a chair, you'll often be, uh, asked to approve a cost share. Um, cost share is anything that is. Requested in the budget of the grant that the grant will not cover, either because, um there's just not enough money, or your investigators exceed the NIH salary cap.Um, uh, some… a lot of, um, foundations and… and non-NIH federal agencies also use the salary cap. State agencies use the salary cap as well. Um, so… so that's something that's important to check. Uh, so you'll have to, you'll have to make that up. Um, uh, you know. how do you make that up? Any way that you pay for unfunded time is how you make that up, uh, and that… and that varies from department to department.

Pete Seidenberg : Right.

Richelle Koopman: But it's usually clinical dollars.

Tochi Iroku-Malize: And another thing we have to remember is there's some grants have carryover restrictions, right?

Pete Seidenberg : Oh, yeah.

Tochi Iroku-Malize: So, like, unspent funds, like, they give it to you in different periods, whether it's, you know, annually, some people… some grants will allow you to take that money and carry it over to the next, but some don't, so keep that in mind. Pay attention to that. That's a restriction that may occur. Um, for them, and then publication costs? As well, some places will give, some places may have prohibit some publication fees.

Pete Seidenberg : Yes.

Tochi Iroku-Malize: Uh, so you have to think about that. And the pre-award spending. Because if you're supposed to start, and they say there's some costs that are gonna… you're gonna incur before you get started. Uh, some may allow that, some may not, so keep that in mind as well. Read the fine print! So, read the fine print.

Pete Seidenberg : And, and your grants management office and Office of Sponsored Research will… will really help you with that.

Tochi Iroku-Malize: Yes. So, yeah.

Richelle Koopman: Yeah, they generally don't let you go astray.

Pete Seidenberg : Um…

Tochi Iroku-Malize: Oh, no, because again, they have a dashboard.

Richelle Koopman: I would say that they generally have very prescribed ways of reimbursing participants, uh, or, you know, giving the participant incentives. Uh, cash is very much not preferred. Um, yeah. Gift cards will generally take a lot of hassle on that. E-gift cards, they like a lot better.

Pete Seidenberg : Oh, that's interesting. Um, so…So, I'm a PI and…I'm trying to create…A staffing budget and an overall budget for this project, and I'm in your department. what do I need to understand. So that I don't completely wreck everything else in the department. Um, I know that's a load grandiose. But, um, so what are some…common things that I need to be aware of that I wouldn't necessarily think about when I'm saying, okay, I need this type of person, I need this type of person, I need this type of person, and this is going to cost this much, and this is going to cost this much, and this is going to cost that much. Gimme, gimme, gimme.

Richelle Koopman: It costs more than you think because fringe benefits, typically around 35% of… on top of… of the salary. So, um, people forget that, and they under…

Pete Seidenberg : That's a great point.

Richelle Koopman: You know, if they're doing it on paper. Uh, they… they get it wrong, and then you don't have enough money. Um, yeah.

Tochi Iroku-Malize: Right now.

Richelle Koopman: Uh, uh, don't forget the people who will do the work. Right? You got your faculty, yes, but, um…You might have trainees, but, um, probably you'll need some research assistance. Uh, and… and they should be funded. Well, because they'll probably be doing most of the work. Um, don't forget publication costs. Don't forget, travel to meetings to present your work. Um…And the money goes a lot faster than you think all the time. I mean, I'm…pretty experienced at writing these budgets, and it still goes faster than I think. And there's always less than I think. Uh, so, um…Yeah, I think those are the things that… that…That trip people up, that I can think of. Tochi?

Pete Seidenberg : Toshi, think of anything else?

Tochi Iroku-Malize: No, I think you're… I mean, you really said it, um, and then, especially if you're using clinicians or someone else, um, that already has a role. How do you backfill that? So doing that… because, you know, everybody says in-kind, in-kind, in-kind is not true.
Pete Seidenberg : Right.

Tochi Iroku-Malize: So, uh, keeping that in mind, whoever else is going to be doing this, uh, work, because for us, we don't have a lot of people who are just purely researchers. They're doing research and clinical, um, work, you know, things like that. So, um, just… Yeah, it's… people cost more than you think. Um, and even when you think, say, administrative staff, uh, that are going to help with certain things. Whatever they're doing, and especially if they're not clinical, they're purely administrative. If you're asking them to take on this piece. Who's backfilling the work that they were supposed to be doing? Um, so how… always think about that backfill if you're using a person who already has a salary. Because you say you're carving out this, and you know, you're playing around and doing all these things. No, so just…Keep that in mind. There's so much going on, and…um, and then also conflict of interest, just keeping that in mind as you're doing as your new PI, and I want you to know what's going on.

Pete Seidenberg : Right.

Tochi Iroku-Malize: Globally, if I have to tell you, just reach… I want you to talk to me as a department chair so I can tell you. Hold on, this thing that you're interested in? the whole… our organization has decided to go in a whole different direction, so don't even bother wasting your time applying for this, or thinking about that, or… you know, there are so many… so just so we… you know what the big picture is, is sometimes important, just having that conversation, so I can say, oh, wait, or yeah, this is great, you know, do this, you know, whatever. So just reach out to your department chair so that you know what's going on, so you're not…Um, you don't… I don't want you to waste your time either, right? So…

Richelle Koopman: A lot of times, people underfund. Themselves, or they're, um, or…

Tochi Iroku-Malize: Yeah?

Richelle Koopman: you know, just globally under… or staff. Because there's not enough money in the grant to do the project. Um, well, that's a problem. Anyway, like, maybe you didn't scale the project appropriately for the funding mechanism. But if you are gonna go and do that. Put in what you really think it takes, and then ask the department chair to cost share that.Don't just say that you're only, you know, in at 5% when it's going to take you 20% effort. Like, talk to your department chair about that, because your department chair is going to come back to you and say.

Pete Seidenberg : Right.

Richelle Koopman: What are you doing with all your time? Because you only have 5% represented on the grant?

Tochi Iroku-Malize: Correct.
Richelle Koopman: Um, you know, we need to know about that. It's really important for staff, too.

Like, uh, people do this all the time with an analyst. They fund the analysts at a very small amount, but it actually costs more, and then people come and they say, oh…the analyst isn't available, and then you look at the analyst, and it's like, why isn't the analyst available? They're only 40% funded. But they're actually doing 80% work, right? Uh, but they didn't… but since it's not represented anywhere, then… then people ask, you know, questions about that. The other thing that I see people doing is, um, you know, cuts after the grant are, um, are commonplace now. So, you know, oh, we're gonna give you this grant, but you have to cut your budget by 20%. Uh, if you want it. Right? So, uh, people will cut themselves and people in the department and leave people in other departments whole, because they don't want to have that conversation, and that's just…Like, no, everybody gets cut and the person who should be least cut is the PI, because the PI is the person who. Who, you know, did all the work. So, um, yeah.

Pete Seidenberg : The other thing that I've noticed is, you know, in some institutions where resources are centralized. There's often a cost share to that and… and factoring in what that cost share is into your budget, I think, is also…Very important. Well…Our time has just flown, so thank you so much for being a part of this panel. Um, and thank you, everyone, for joining our session on navigating regulations and compliance to increase research in your department.

Pete Seidenberg : Um, thank you…Uh, again, to our panelists for sharing your experiences. And, uh, please check out the other sessions for the department chair's curriculum on research, the other sessions are on ecosystem, infrastructure, and funding. Thank you all again, and have a great day.