How Changes to Title 2 Code of Federal Regulations Affect You

>> Michelle Bulls: This is Michelle Bulls; I am the Director for the Office of Policy for Extramural Research Administration here at the NIH. And I'm joined here with my colleague and friend, Kristin Ta.

>> Kristin Ta: Hi, I'm Kristin Ta. I'm a Senior Advisor also in the Office of Policy for Extramural Research Administration or OPERA.

>> Michelle Bulls: So we’re going to talk to you about how changes to the Title 2 CFR Part 200 affect you. So Kristin, let's go.

>> Kristin Ta: Alright. So the first question we always get when we tell folks we're going to present about Title 2 is, what is Title 2? So can you tell us a little bit about that, Michelle?

>> Michelle Bulls: Title 2 is a direct regulation out of the Office of Management and Budget. We are excited to be linked and connected to OMB, which connects to the HHS Office of Grants Policy. And so for us, we are looking at implementing Title 2 within NIH, the way OMB has outlined it in whole cloth. We also support the HHS Office of Grants Policy and Administration. So whatever the Office of Grants does that's what NIH does, but we want to bring it to you from a research perspective.

>> Kristin Ta: Great. And so Title 2 applies to all agencies or just some of them?

>> Michelle Bulls: Title 2 applies to all agencies that have grant making authority. They also make sure that the requirements are related to not only administrative requirements but cost requirements. And it originally started in 2014, when 2 CFR Part 200 came out from OMB. And now what we're looking at is adopting that from all across the federal platform; whether it's research, whether it's community based, no matter what OMB is the directive and that's what we apply it to.

>> Kristin Ta: Cool. So these are pretty huge regulations. What was the process for coming up with all of these updates and making these changes?

>> Michelle Bulls: So I’ve got to tell you, we have colleagues and very good friends within NSF and across the research platform that said that all of the changes were very limited in scope. Over the past year, OMB has worked with other agencies: HHS, NSF, DOD, others at the department highest level to identify and make changes to Title 2 CFR Part 200. NIH, as a matter of fact, will take whatever HHS does and adopt it in a way that makes sense for the research community. We fought and worked very hard and close together with OMB and NSF and at times with HHS to identify research perspectives that would make a difference or make a change for 2 CFR Part 200 as it relates to our requirements. Most of the changes will be effective November 2020. But, well, there were a couple right? There were a couple that were effective in August. The telecom and what was the other one, Kristin?

>> Kristin Ta: So telecommunications was one, and termination. So those were effective immediately.

>> Michelle Bulls: And those were the two.

>> Kristin Ta: Yep. And we have -- but we'll cover both of those a little bit later.

>> Michelle Bulls: Very good.

>> Kristin Ta: So you mentioned that 2 CFR is kind of at the highest fed-wide level, so where does NIH fall? How do we implement that down all the way for our recipients?

>> Michelle Bulls: So, for us, and I think it's very important for our recipient community to understand that NIH serves under the umbrella of HHS. So what does that mean? That means that HHS sits at the table provides extreme expertise if you will, for community based grants for Title 2 and allows the OMB to understand from a perspective of what HHS does versus what NIH does. And it's all the same, to be quite honest with you. Right? So for us, legislation is top of the line then at legislative requirements, we don't have deviations. We don't have a way forward. If the law says we have to do it, we do it. And then we go to regulations, which you highlight here. And we are here. So 2 CFR Part 200 allows HHS to implement it in 45 CFR Part 75. And what we recall is 2014, HHS said, "we're going to implement all of those requirements from 2 CFR Part 200 in whole cloth. And by the way, agencies, if you want to do something different, you need to request a waiver." So we did request a waiver in some instances, didn’t we?

>> Kristin Ta: Yep, definitely.

>> Michelle Bulls: Right? So we requested a waiver for indirect costs. Because how many of our indirect costs require that we do the de minimis versus the 8%. So we said, not so much we want to make sure that our foreign entities, our training grants, and others that don't -- conference grants that should not, get an F&A. Right? We asked for deviation there, and HHS graciously gave ithat to us, as well as OMB. So then when we move down to the order of precedence, what NIH has is HHS policy. So HHS policy always adopts the regulation in whole cloth, unless there are deviations. But NIH has had an opportunity in previous administrations and the current administration to adopt regulations and policies that allow us to move differently in the research space versus the community based grants. And why is that different? Because the way NIH does things for F&A for direct costs is very different from other agencies. And then, so NIH has had a, what we call a waiver or deviation from the HHS policy that allows us to do things just a tad bit differently to allow for our research grants to move a little differently than our regular grant programs across the department. So what we hear is, why does NIH get to have a NIH Grants Policy Statement? Or why do you all have a different policy? We don't have different policies. We align ourselves very closely with HHS, except for where there are differences that may impact or negatively impact our research grants and those are where we have deviations. So we have statute. We don't deviate from that. We have regulations. We really don't deviate from that. We have HHS policies that we request waivers and deviations from to allow our programs to function.

>> Kristin Ta: Great. And so now that we've got the 2 CFR updates, as you mentioned, the next step, HHS will be implementing that at 45 CFR 75. And then we're working at NIH to go through those Title 2 changes in detail and make sure we catch every change so that we can update our NIH policies accordingly. And that's all going to be coming in our NIH Grants Policy Statement this fall, right?

>> Michelle Bulls: Yes.

>> Kristin Ta: Great. So now we're going to go through some of the changes in a little bit more detail. And I know there were a few that you personally were really pushing for as our NIH Chief Grants Management Officer, where we've gotten some big wins for our recipients. And the first one, if you want to go over that is the micro purchase and simplified acquisition thresholds.

>> Michelle Bulls: So I think many folks understand that we worked with COGR, we worked with FDP to make sure that the original regulation and the spirit of that regulation was aligned. So both on thresholds were updated in 2018. The original threshold was, you know, the micro purchase threshold was $10,000. Simplified acquisition, $250,000. Now we have an update in the regulation that matches to the simplified acquisition threshold. We're very excited about that. We were very concerned initially that we had such a small amount. And I don't know that folks understood that from the institutions of higher education to the nonprofit research institutions there's a very different model, and a very strong model, within our partnerships that varied from state and local governments, tribal governments. And while we respect and appreciate all of the differences between those two, we also wanted to make sure that our folks had a high enough threshold that we would not put them at audit risk. And this has maximized that concept. So we minimize the need for future regulatory updates. As the dollars change in the FAR and other places, then we just roll along with those changes, but we don't have to make differences in the 2 CFR Part 200. And that is an amazing win. And I just appreciate OMB and NSF and others that sat on the group that helped us move these changes forward. And I really appreciate them.

>> Kristin Ta: The next one is another one where you mentioned working with COGR. So this is one where you've really worked with, agency partners, COBR, everybody. And that's related to subrecipient monitoring.

>> Michelle Bulls: Yeah. And I think for that, we have to give some credit to HHS and the previous leadership to say that subrecipient monitoring was nothing different. We just wanted to make sure that there was a clarification. And this is what they’re providing. So 200.332 now allows for that clarification. NIH and NSF, working in partnership, as we always do on many occasions, collaborated to develop these changes. And then we worked with COGR and FDP and others to say, “Is this what we really mean?” Because, again, another situation where we were not clear, and we had put our colleagues and partners in a risk for audit. And so for us, we were excited to make that difference. And I think that OMB and others are very excited as well. And they were able to deliver that to our community.

>> Kristin Ta: Yep. The next one, I think, is my personal favorite, cause I know it's a project I've worked on a lot is related to closeout.

>> Michelle Bulls: We should talk about that.

>> Kristin Ta: So this one, it's not a huge change for-

>> Michelle Bulls: What did you do? What did HHS, OMB and others do to make this happen?

>> Kristin Ta: Yeah, so closeout has been something that has really been on the radar of HHS for years now. You know, timely closeout of grants, making sure reports are submitted on time, things reconcile in the financial systems and all that good stuff. NIH has had flexibility in place for a while where our recipients have had 120 days after the end of the award to submit all of their closeout reports. And that's something we've really been pushing for on a broader level is we said this works for us, we like giving folks this additional time to get their invoices from subrecipients and you know, make sure everything is good to go when they close out. And so now that flexibility is being put actually into the regulation, so that all the agencies can offer that additional time for both submitting the reports and actually completing that final closeout, which hopefully will help us cut back on all these really old grants that just end up sitting open forever and ever because things don’t reconcile.

>> Michelle Bulls: So the other piece of that, in addition to all the work you've done is, you know, initially we had a situation where we were aligning ourselves and wrapping ourselves around ourselves, in that we were doing the 270 days. And so why not align with all the other agencies for the one year and giving our recipients an opportunity to maximize, not only just 120 days, but the closing of awards for the performance period for one year. That, to me, is huge.

>> Kristin Ta: Yeah, I think this is the area where we're going to see-

>> Michelle Bulls: [INAUDIBLE] work on that.

>> Kristin Ta: You were pushing for it even before I got here, so.

>> Michelle Bulls: That’s okay.

>> Kristin Ta: All right, so now we're going to go through a few other changes that are going to impact our recipients. The first is some updated definitions. Do you want to kind of give an overview of what's going to be changing?

>> Michelle Bulls: I'm going to give that to you.

>> Kristin Ta: So really what OMB was trying to do here was, there are a lot of terms that folks use widely in the grant community that have never really been captured in the regulation. And so the goal here by adding definitions for things like budget period, discretionary award, notice of funding opportunity. I mean, these are terms we use all the time, and by putting them in the regulations, we're going to make sure that everybody's using them consistently across the board, so that we're all kind of working from the same.

>> Michelle Bulls: The [INAUDIBLE] is are we changing, NIH, the definitions? Like so it says, new definitions and updated definitions. So for NIH's community we've had a definition of budget period discretionary, renewal, even notice a funding opportunity, non-discretionary award. Is that going to look different now that we've updated 2 CFR 200?

>> Kristin Ta: So most of the definitions we have at our NIH Grants Policy Statement, already lined up pretty closely with the definitions that we're seeing in 2 CFR. So while we might see some slight tweaks in wording we're not going to see what you know, terms that suddenly have a completely different meaning. It might be some small changes but for the most part we already aligned with. And we shared our recommendations for what the definitions should look like so it shouldn't be anything that's too surprising.

>> Michelle Bulls: Okay. And we're going to have that in the revised NIH Grants Policy Statement?

>> Kristin Ta: That's right, coming later this fall. Okay, so I know this was a section that we had some challenges with and made some recommendations on, which is related to performance. And they're kind of throughout the whole regulation. They've been updated in a couple of places. So do you want to talk us through a little bit what's changing here?

>> Michelle Bulls: So, I guess for us we're just tracking the performance piece of the RPPR, right? And I don't think that there is a lot of difference except for we have outlined the fact that there's a pre-award, post-award, and closeout. And so through the life cycle, the goal here is to recommend that there is a program design that clearly outlines the goals and objectives for the entire project, right? And for us, we just need to make sure that when we are putting our requirements in the terms and conditions -- or no, so -- we put terms and conditions in the funding opportunity announcement, right? But we also outline what those goals are from the beginning to the end. But also within the FOA there are terms and conditions, because the beginning is the end, and the end is the beginning. So we have to make sure that the program design clearly outlines what we expect that research project to do from beginning to the middle to the end. And so for us, we've not always included that because from a research perspective, a large part of what biomedical research does is we don't necessarily know until we test it. And so for us, we have tried to at least show that we're interested in knowing what the program goals are, what the program design is, but we may not know the outcome of the research until the end. And that's very fair. So what we're doing here is putting a program planning and design section that will help us identify, you know, what is it that we anticipate at the beginning, that we can look forward to the end? And that might not be always clear for research, but we're going to try to work through that so that we have performance measurements that outline the differences on a program by program basis. And I'm not sure that we know what that would look like at the beginning, but we certainly know what that will look like at the end.

>> Kristin Ta: Yeah, I think this is one where it really shows the difference between research and other types of grant awards.

>> Michelle Bulls: It does. It does, but I think we can as a research agency, not outline what we expect the research outcome to be, but we also outline what is the program plan and what does the design look like? [INAUDIBLE] that information at the outset, sometimes people can get to the end, before the beginning, maybe. I don't know.

>> Kristin Ta: Okay, and another one. Go ahead.

>> Michelle Bulls: So we were talking about the standard data elements. And we've had this in the past. I think this is just another instance of us trying to improve and maximize what our application information looks like at the outset. What would you like to say about that?

>> Kristin Ta: Yeah, I was just going to say the standard data elements. I mean part of the reason for this whole round of updates to the regulations is the, you know, the President's Management Agenda, which is really pushing standard data elements, you know, streamlining as much as possible, those kinds of things. And I think you can see this is tied directly to that -- trying to make things standardized as much as we can. I mean, obviously, research is a little bit different than a lot of other things. But there's still areas where standard data elements can be used.

>> Michelle Bulls: How does that look for standard application requirements and financial reporting? And the reason why I asked that question is because as we adopt and move into this, we need to make sure that our research community understands these are government-wide data elements. These are not NIH or just research data elements. How does that look?

>> Kristin Ta: I think for standard application requirements and financial reporting, I mean, you're really going to see that for the most part these things are already done pretty consistently with things like the SF 425, and the RPPR forms. So really, it's just going to be kind of kicking that up a notch and making sure that we're really using all of those tools consistently fed- wide.

>> Michelle Bulls: Yes, there. Okay. And awarding agencies in must show said certain things in that FFR. So we need to be clear about that as well.

>> Kristin Ta: Yeah. All right. So prohibition on certain telecommunications and video surveillance services or equipment. This one is a bit of a mouthful.

>> Michelle Bulls: When are they going into effect?

>> Kristin Ta: That is in effect already. It was immediate when the regulations were published back in August.

>> Michelle Bulls: So for us, I think what we will say here is that we fully expect that as we obtain additional information and requirements from the department, we will give additional information to our recipients.

>> Kristin Ta: Absolutely. And I know you've been working closely with HHS on what that's going to look like. So we will provide updates as soon as we have them. And then kind of on a similar vein is domestic preference for procurements, which folks have probably heard about, you know, by its acronym, the BAHA requirements. So you want to explain what those are?

>> Michelle Bulls: So I want to kick that one back to you. I think you're better on that one than me.

>> Kristin Ta: So I mean, this isn't really anything different from a lot of the things we currently require, you know, like the Fly America and those types of initiatives. So essentially this requirement is emphasizing the importance, you know, to the greatest extent practical that our recipients are looking to purchase goods and products that are produced in the United States. I mean, it's obviously not something that can be done 100% of the time, but it is something that is being emphasized for our recipients. And that also will flow down into sub awards and consortium agreements and that type of thing.

>> Michelle Bulls: So those two have been as always as the prime, but then that flows down to the sub awards.

>> Kristin Ta: Okay, I think this might be the last one we've got, which is appropriate because it's termination.

>> Michelle Bulls: Ending. [LAUGHTER]

>> Kristin Ta: And this is another one that was effective back in August.

>> Michelle Bulls: Right. And so, for the termination this something that's been really critical and we've identified this in our procurement contracts, right? Where the agency via HHS, our umbrella, the OMB has updated our language here to strengthen the fact that we are able to terminate awards that no longer effectuate program goals and objectives. And I think this is a really good one in that there are times where we need to terminate our grants in whole or in part, because it no longer meets the program goals and objectives of our agency priorities. And this is something that has been huge across the department and across the federal spectrum. And I think for us, we need to make sure that that looks like initially, we want to bilaterally terminate because we always want our partners, our recipients, to be in agreement with anything that identifies something that doesn't meet the needs, or the requirements of the terms and conditions first, and of the agency second. We also do that in accordance with our regulations, where we would send a letter or a written notification notifying our grant recipients that this is something that we believe is a need. So we set out the requirements, the justification for termination. And then if partial or in whole, we want to make sure that our recipients get that piece as well. And then identify what we want to do next. Is it that we want to bilaterally terminate? Maybe. Because we want to make sure that our recipients are good with that. And if not, then we move to the fact that this grant or agreement has to terminate because it no longer meets the agency's goals. And as a grant making agency, we have to make sure that whatever we do, it maximizes the mission of the agency. And when it no longer maximizes the mission of the agency, then we have to terminate or seek resolution. So that's where this comes from. 200.345.

>> Kristin Ta: Great.

>> Michelle Bulls: And with that, we do look forward to the updates from 45 CFR Part 75, which will be implemented through NIH Grants Policy Statement. We anticipate that the changes will be in existence by November. And as always, we're here to answer questions, either through the Division of Grants Policy, to outline the policy statement issues, compliance and oversight, helping you understand how to maximize and effectuate your terms and conditions. And then the System's Policy Branch, which is our new arm, that outlines all of the application instructions and form requirements. And with that, I don't have much more. What about you, Kristin?

>> Kristin Ta: I think we've covered it, and now we can take some questions.

>> Michelle Bulls: Thank you.

>> Kristin Ta: Thank you.

>> Michelle Bulls: Thank you.