IRB Updates_ Changes that may impact the IRBNET submission-20240913_120132-Meeting Recording

0:02
Juan, and thank you so much for joining us today.

0:06
My name is Doctor Roberta Christopher.

0:08
I'm the Chair of the IRB and a faculty over the nursing department.

0:12
And then Dr.

0:13
Clarabelle Torres is also with me and she's our compliance Officer for the Board.

0:20
So the board has been working hard over, I'd say, the last year on this determination form to really streamline processes and forms for faculty and students.

0:33
So thanks for all of your feedback and we hope that this determination form will be accessible and easier for you across all different kinds of programs and discipline.

0:47
So I'll turn it over to Doctor Torres to give you some foundational information, and then we'll go over the form.

0:56
Thank you for having us.

0:59
Can you see this, this the screen?

1:02
Is it the way is it?

1:04
I can't correct.

1:05
Yeah.

3:52
Oh now do you do I need to share my screen and do the slides?

3:58
How about if you can do that, because I am totally frozen from here all right, let me if are you able to stop sharing Let me see if it'll let let me see if it'll let me take over.

4:16
Are you able to see my screen Now?

4:22
You can I just I see I see our friends, but I don't see the Yeah, I see.

4:29
I see your screen, Berta.

4:32
OK, I'm on slide 2.

4:34
What is research and what is human subjects research?

4:37
OK, so now it's not showing.

4:40
Now it's not showing.

4:41
You need to share, maybe share that.

4:44
Let me re Yeah, let me re share.

4:52
How about now?

4:52
Do you see it now?

4:54
Yes.

4:55
OK, see it now.

6:31
And interactions for the most part include your surveys and your interviews.

6:36
Interventions are, you know, how you manipulate the participants environment in in an effort to elicit some sort of response, right?

6:46
So and then you go ahead and you use that information and that data in order to answer your research questions or your objectives.

6:54
Now there is another level of what the code for their regulations definition of human subjects, and that is just using private information, which means that you're not necessarily talking or reaching out to a human per SE, but you're using their personal data.

7:16
And according to the code of Federal Regulation, that falls under what they call human subjects research.

7:22
Next slide, please.

7:25
All right.

7:25
So that said, once we have a clear understanding of what those two constructs are, the next question is when should I use this form?

7:34
And that's going to be a question that's going to come across a lot.

7:39
The form, it's designed to help researchers when they are uncertain if the project missed both the definition of research and human subjects research.

7:53
If you are unsure the determination step is right for you, please contact us for additional information.

8:00
Next slide.

8:04
So where I can find this determination form?

8:08
This determination form has been posted in the forms and templates in IRB net.

8:13
So that's where your students and yourself will have access to it.

8:18
Next form.

8:21
Well, my student and I have completed the form.

8:24
So what's gonna happen now?

8:25
The process of submission is the same as you are familiar with.

8:30
You will submit that determination form through the JU IRB net and once most likely I will be taking a look at that form and if need be, I will submit to an IRB review for a final determination.

8:48
So the process remains the same.

8:51
And just to add to that, so if for example, I may have as a as a faculty chair several students, I'm working with each application, each student would would need their own package in IRB net.

9:08
So we wouldn't be able to take a where a faculty would submit like 8 or 10 forms that in one package.

9:16
So each is, each is treated as a separate project and determination and determination.

9:24
Yeah.

9:24
And the reason for that is, is that, you know, each submission is unique.

9:29
So researchers may need to provide feedback, more subsequent feedback in one form that it would be in another form.

9:37
So we want to make sure that we're not bombarding everyone on this package, which could be confusing for students.

9:44
I got this e-mail about the package.

9:46
Is it me or it's not me?

9:48

So once we have made that determination we will give you a letter for your records and that way you

16:10
We've got some language here for like the business data sets and such or CDC if you're in healthcare as some guidance there.

16:21
So if it's not secondary research, you can go down here to check which activity it might apply to.

16:31
So in lieu of the the Qi program evaluation form, if it's if, if you think it's not going to meet research definitions or what have you used this instead?

16:44
So you can check for quality assurance if the, if it's program evaluations, if you're doing surveys, oral history, artistic works, and we've tried to make these categories work that are the most common ones the board was seeing that would would fall under this type of approval.

17:06
If you're not sure other you can tell us what the design is or what kind of project is and we can, we can help with that.

17:15
This section is crucial here because this is the information that the reviewer will need to be able to make that determination.

17:24
You know, a detailed description of the project, what are the objectives and aims?

17:29
That can tell us a lot.

17:31
What type of data will you be collecting?

17:34
What?

17:34
What I've been doing, I've had a couple come through.

17:37
What's helpful for some of these?

17:40
Or if you're looking at data sets that are publicly available, you can include the links.

17:44

That's very helpful because we could easily click on those and see, yeah, this is, you know, publicly available stuff.

17:51
There's no identifiers.

17:54
How will you collect the data?

17:57
So some things that the reviewer would be looking for, like with Facebook for example, sometimes we're recruiting through there is are we recruiting to just open source Facebook or in a private group?

18:11

20:57
But if you're not sure of any of these, just check with us.

21:01
And then the next thing is the living individual piece, human subjects, you know, so are are you going to be doing something with some humans?

21:12
And so you can check what would apply there.

21:16
And so that's basically the form and the final pieces, that private information piece of the definition is this.

21:25
Could we individually identify these individuals?

21:30
So that's the high level of the form.

21:32
So I'll turn it over to, do you have any questions or anything that you'd like Clarabel or I to go over in more detail?

21:42
Go ahead.

21:43
Doctor Holloway.

21:46
Well, first of all, thank you.

21:47
I, I think this form is much easier to understand and follow the process from one who has to call Doctor Christopher on a regular basis, say, hey, did I fill this form out correctly?

22:00
The form though, is this going to take the place of the application form?

22:06
So for example, right now I'm working on one and do I still put in like I think it's going to be expedited instead of exempt?

22:15
Do I, I still, I fill up this form and then I go ahead and fill out the application form for the exempt.

22:21
So that's a kind of a loaded question.

22:24
Let me back it up a little bit.

22:26
So no, it's perfect.

22:28
It's exactly what you need to be asking.

22:31
If you already think that your package may go exempt or expedited, you may just need to go ahead and do that particular application.

22:41
OK.

23:48
But that's what this form also helps, helps you with, right?

23:52
So if you're not sure you could do it and then the reviewer and Clarabel or I will look at it and say, hey, you really should go ahead and do exempt or expedited.

24:01
If we have enough information in the application and we can determine it meets one of the exempt categories, we might be able to go ahead and approve it, you know, as exempt.

24:13
But that would depend on how much information was, you know, provided that we would be able to,

25:27
Clarabelle, what do you recommend as well?

25:30
Yeah.

25:30
I mean like I said, if this form is available to you and it's available if you're uncertain about which way to go, rather than have to submit a package and then we telling you, oh maybe you should have not have send this, this is not even human subjects etcetera, etcetera.

25:51
You know, it's up to you.

25:52
I mean, if you're certain that your protocol fits within the exemptions or the expedited form, go ahead and submit it.

26:03
You know, there's no harm in you using the 33()12652F3 9.98871 0 595.32 841.92 reW*nBTF3 9.96 Tf1 0 0v2sb. Tm0.196

28:32
All right, thank you, everyone.

28:34
Have a wonderful weekend.

28:35
And then we'll be sending out a follow up e-mail to all faculty that will include this presentation as well and updates.

28:43
So thanks so much again.