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Stakeholder Views on Novel Consent Forms for an Acute Stroke Trial

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Table 1. Consent Form Themes

Consent form		
Theme	**Quote**	**Participant**
Length	"I think it's not as overwhelming. A lot of information is thrown at 'em really quickly, and because it's so short and concise, I just think it makes the idea of wanting to be in research a lot easier to grasp at the time."	Coordinator
Essential content	"I feel like a lot of interventional trials are almost informational overload and the length of the consent I feel like is appropriate for the information that needs to be relayed, but also respecting the time constraints and not overloading the patient with unnecessary information."	Coordinator
	"The feedback in general is the MOST consent form is much better, it's more	PI

	wieldy than consent forms that I've seen. We have these huge fights with our IRB 'cause then they try to go back and add in five more pages about the risk of the CT scan or something that all the patients are getting regardless of whether or not they're in the trial. I do really appreciate that"	
	"This may not hew to our normal process here, but are we hitting all of the elements of consent that are appropriate for this population at the appropriate time for this population, and I appreciated the tailoring of this process given the potentially urgent environment and the use of a community advisory committee to develop that."	IRB/HRPP
Clarity	"It's a dense study to take in at the beginning, but I think it does a pretty good job of laying out the essentials in understandable language."	Coordinator
Organizational structure	"…the way that it's laid out, and which things are either underlined or bolded or indented in such a manner where it talks about the specific arms of the drug… It stands out more than my other consents,	Coordinator

	which is just a whole bunch of words on the paper that go on and on."	
	We didn't require a lot of changes, because it was structured very well. So all we needed was to just add in our local language into it.	IRB/HRPP
How it is used in practice	"When I consent for MOST, I give a little debrief of what the study is before I actually go into the consent so that they can think about it, and if they want me to explain further, then I'll go into the consent form. By the time I'm done giving my debrief, I've explained the majority of the consent at that point, and then I just go through the consent and hit those key points that I have not already explained, which typically end up being the very specifics about how the drug's gonna be run, the risks, the benefits, and who to contact in case of emergencies, when we'll see them in follow up, and some of those key things."	Coordinator
	"This has tables in it, and indentions, and bullet points, so when you're searching	Coordinator

	for—when someone asks you questions, and you're searching for answers for the consent to answer their questions, or if a patient or a family member is like, 'Oh, I wanted to talk to you about this. Let me find this,' I've just noticed that me myself other coordinators or family members can flip through that easier because things just pop out a lot easier in this consent versus the other consents that I deal with. I think that just has to do with the way the consent looks."	

Table 2. Information Sheet Themes

Information sheet		
Theme	**Quote**	**Participant**
Detailed	"I do not think I would have had to rewrite. It's very well thought out. It is explained very well."	IRB/HRPP
Organizational structure	"I like the table that's in the sheet that has—especially when it stamps out when the different visits are as well."	Coordinator
Function compared to consent form	"Some people just don't even need that stuff. We give it to them, and then it's	Coordinator

	never looked at again. Some people are pretty invested in understanding what's going on and stuff. I think, having that take-home thing that's separate from the consent form, that is specific for information, not explanation of research but information about the study 'cause I think people get a 20-page consent form, and they're like, 'This is all legal jargon. I don't wanna read this.' Yeah. Instead, the supplementary information is more like, it has a table layout of everything they're gonna need to know, which is, I think, helpful for people 'cause I don't think everyone's really inclined to read—nobody reads the terms of agreement or anything."	
	"I actually agree with what you did, with including it separate. …you have to look at the fact you have a 30-page consent form, which in any condition no one's going to understand or read through the entire thing."	IRB/HRPP
How it is used in practice	"Usually, in our binders, I have three sleeves that the consent, the HIPAA, and	Coordinator

	the study info sheet goes in. I pull all those out. Then once we're done signing the consent form, I—if they are able to take the paper—sometimes they don't want to 'cause they're going to get ushered back or something, and I'll say, "I'll bring it to you when I have a copy of your consent form." always give them the option. Some people don't want it immediately though.”	