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Saying Yes

When mortgage rates were lower, my husband and I decided to refinance—a couple of times. Each time, we called our trusted banker who set the wheels in motion. We sent in the required documents to show that we were worthy, and after a couple of weeks, a date was set with a representative from the title company to sign the paperwork. At each meeting, we encountered a mound of paperwork that the representative guided us through, getting our signatures or initials at all of the required places. Do you think we actually read anything we were signing? Of course not! We trusted the bank, and frankly, we were just eager to get it over with and get our lower monthly payment set up.

I think many of us feel the same way; we are busy and we don't have time to wade through complicated legal documents. For example, who ever reads the 'Terms and Conditions' when you're working on the Internet? You just need to do it, and do it now!

The stakes are higher when you're a patient with cancer considering a clinical trial, of course. But I think there are some similarities. Informed consent documents are impossibly long and detailed. I belong to an international group called ARCAD (Aide et Recherche en Cancérologie Digestive), which focuses in part on improving clinical trial design in gastrointestinal cancers. We recently published a White Paper[1] discussing the critical need to simplify the consenting process, including the informed consent document itself. While I agree this is needed, I wonder how much of an impediment this really is when it comes to clinical trial accrual.

I've been enrolling patients onto clinical trials for a long time. My own observation is that it's often my enthusiasm for the scientific question that drives accrual. Patients trust their physician just as I trusted my banker in my initial example. If I think a clinical trial is a good option, chances are the patient will too. Consider this: you can approach a patient about a randomized trial and say that, "In addition to the standard of care therapies, you could go on a trial where you are randomized to these therapies or to the same drugs plus new drug X that, in early trials, has shown some activity in your disease. Interested?" OR you can start the conversation this way: "You're really fortunate that we have a clinical trial open that you're eligible for. It involves an exciting new drug that has promising effectiveness in early trials. There's a chance you might get randomized to standard of care, but if the drug pans out, it's likely to be approved by the FDA and will be available for you down the road. Interested?"

Usually, by the time we've covered risks and benefits and logistics, patients are often ready to sign. We don't let them do that right away, because I think everyone should sleep on a decision like that. But my point is that I don't think it's the consent form that turns them off. Either they are not interested in the first place or the logistics (eg, extra biopsies or other procedures, or delays in starting treatment for biomarker screening) turn them off. I don't ever remember a patient saying that they won't participate because the consent document was too complicated.

To sum up, yes, let's simplify documents that we expect people to understand across all sectors. But even better, let's use our professional knowledge and our compassion to build trust and understanding. That will take us farther than any written document can. Go for it!

Reference

1. Bleiberg H, Decoster G, de Gramont A, et al. A need to simplify informed consent documents in cancer clinical trials. A position paper of the ARCAD Group [published online ahead of print February 13, 2017]. Ann Oncol, doi: 10.1093/annonc/mdx050.

What do you think? Please e-mail correspondence (include contact information) to JNCCN@nccn.org or log into www.editorialmanager.com/JNCCN to submit a Letter to the Editor.

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