

Coercion and Undue Influence: The Worst Consent Ever?

By Norman M. Goldfarb

Imagine you are an investigator conducting a study with eligibility criteria that are tougher than you had anticipated. The sponsor is threatening to close your site before you can recover your start-up costs. You enter an exam room and greet your patient...

Hi Jim, I hope you are well today. I'm running behind schedule, so I have just a few minutes before my next patient. Before we talk about your chest pains, let's discuss the alopecia study I mentioned before.

You're really lucky to be getting this invitation. I'm not letting just anyone participate in this study. It's a great new drug for treating baldness. I wish I were bald, so I could be in the study.

If you don't want to participate in the study, that's okay, but you may not get invited to the next one. And I do try to give study participants preferential treatment in appointment scheduling and such.

Now, to qualify for this study, you can't be taking any hair-growth medications. That's correct, right?

My friends at pharmaceutical company are very excited about how much better this medicine is. And, of course, we all know they wouldn't be paying for this study if they didn't have a pretty good idea that it works as promised.

I hear the FDA may approve the drug early, but you, my friend, will get it even earlier. In fact, they are even talking about whether it might spice up your love life.

A few participants will get a placebo, a sugar pill, but I think I can pull some strings so you get the real thing. My patients already on the study are responding very well.

This is what we call the "informed-consent form." I've examined it carefully so you won't have to read it. I can assure you that I'm fully informed about the study. Just sign at the bottom, and you can get out of here.

Those side effects? That's just boilerplate. The FDA makes us put those in to cover the bureaucrats' rear ends. Have you ever read a drug label? Life is full of risks; drinking too much water can kill you.

In addition to more than \$10,000 in free medicine and medical care, we're going to give you \$50 a visit. It can't get much better than that. Well, actually it can; after we talk, let's take a walk over to the sample cabinet and see what we can find.

I know you're still a bit hesitant, but I definitely want you to sign up for this study. It's important for our community, and we all have to do our part. I know you're better than other people who just want a free ride on medical science. We still need to talk about those chest pains, so, whenever you're ready...

By the way, if you can round up two friends to join you in the study, we can all go out on my boat next Sunday.

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