

Contributed by Norman M. Goldfarb

NORMAN M. GOLDFARB



THE WORST INFORMED CONSENT EVER: HOW PHYSICIANS CAN COERCE AND UNDULY INFLUENCE PATIENTS

Informed consent requires that the potential subject be fully informed and capable of making a rational decision to participate in a clinical study. The attempt to incorporate all of the pertinent information in informed-consent forms has, unfortunately, created documents that are simply too long for many potential subjects to digest, leaving aside the almost unreadable text and arcane vocabularies. Given the impossibility of creating a litigation-proof informed-consent form, this problem is likely to continue. A 100-page informed-consent form may include every pertinent detail, but its length defeats its purpose. Highlighting the most important information de-emphasizes the rest of the content.

FULL CIRCLE

The informed-consent process is thus going full circle, back to the days before written informed-consent forms, when potential subjects relied on verbal explanations by the investigator. The burden is growing on the investigator to verbally provide the information that potential subjects actually want in a simplified, understandable form. Given the increasing enrollment and cost pressures on most investigative sites, the temptation for coercion and undue influence also is growing. Fortunately, most investigators do their best to be ethical. Unfortunately, to my knowledge, no one has yet published a clear and complete cautionary guide to the twin pitfalls of coercion and undue influence, especially one that investigators are likely to read and remember.

WHAT NOT TO DO ...

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 are about to meet with one of your patients to obtain informed consent ... but be careful; do not make the following statements to patients:

RUNNING BEHIND SCHEDULE

I'm running behind schedule so I have just a few minutes before I have to see my next patient. Before we talk about your chest pains, let's discuss the alopecia study I mentioned before.

THE INVITATION

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.

PREFERENTIAL TREATMENT

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.

THE PRESUMPTIVE CLAUSE

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

MY FRIENDS AT THE SPONSOR

My friends at the sponsor wouldn't be paying for this study if they didn't have a pretty good idea that the drug would work. There's some evidence that it may even spice up your love life.

THE FDA

I hear the FDA may approve the drug early, but you, my friend, will get it even earlier.

PULLING STRINGS

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

SIGN ON THE DOTTED LINE

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 this study. Just sign at the bottom, and you can get out of here.

SIDE EFFECTS

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.

THE DIARY

You're supposed to fill out a diary every night, but it's just a formality; we'll give you a hand the next time you come in.

FREE SAMPLES

In addition to the more than \$10,000 in free drugs 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.

COMMUNITY OBLIGATION

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...

THE "FREE" RIDE

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.

Norman M. Goldfarb provides clinical-research consulting, training, implementation, and research services. For more information, visit firstclinical.com.

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