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Consent Form Humor

By Mark Hochhauser

Over the past few years, IRBs have been criticized for taking too long to review consent forms, requesting too many irrelevant changes, slowing down the clinical trial process, etc. In defense of IRBs, I've collected the following emails (edited for clarity) from IRB members that highlight some humorous consent form content.

1. Pregnancy in post-menopausal women

From a study of women aged 55 and older:

> Please discuss with your Study Doctor the most appropriate birth control method for you that also respects your cultural and religious situation. Examples of highly effective birth control methods are…

This consent form also included a lengthy section on risks associated with contraception and pregnancy. Although the IRB asked that the 613-word section on contraception and pregnancy be eliminated or shortened, the sponsor refused, insisting that women 55 years and older could get pregnant.

2. Contraception in nuns

This study required women to use an effective contraceptive technique — combined-drug hormonal contraception, in the absence of established menopause or surgical sterilization. A pre-menopausal nun wanted to enroll in the study. The sponsor did not consider sexual inactivity to be a sufficient safeguard. It insisted that she take estrogen-containing birth-control pills. The nun objected on religious grounds (which are not clear, given her abstinence). The sponsor responded with: "What if she gets raped?"

Based on our research, we estimated that the risk of conception by rape in American nuns was below one in 200,000 woman-years. In contrast, the risk of a serious complication from oral contraceptives was about 7 per 1,000 woman-years, with 2% to 10% of those fatal.

After we objected on ethical grounds, the sponsor uninvited our site from the study.

3. Semen dosage risks for pregnancy

Many studies require gestational exclusion for male participants (with a pregnant partner), even if the only known risk is daily in-utero exposure at high doses. For one such study, we calculated that the minimum risk-bearing exposure (for the most sensitive animal for which data existed) would require the delivery of 2.1 liters of semen (from a partner on the drug) intravaginally daily. Nevertheless, nearly a quarter of the risks section of the consent form was devoted to the need to avoid fathering a child.

4. Men shouldn't get pregnant

This federally funded prostate cancer study warned participants that they should not become pregnant or father a child while on study medications. This was an obvious cut-and-paste error, but the cooperative groups have a strict rule against deleting study risks. The central study coordinator said the language could not be removed, but someone higher up allowed it.

5. Having sex with the researcher

The consent form for this study included a survey aimed at men who have sex with men. The PI wrote the inclusion criteria as "men who have sex with me" instead of "men who have sex with men."

6. Impossible pregnancy

The consent form for this study of an immunomodulating strategy for Grade IV graft-versus-host disease (GVHD) in patients who had undergone stem-cell transplantation (really "trans-" not just an autograft) for relapsed, refractory or high-risk childhood acute leukemia devoted nearly a full page of the consent form to pregnancy protection.

However, pregnancy protection seemed superfluous for several reasons. First, two-thirds of the subjects would be pre-puberty. Second, at the time, allografts left at least 95% of patients sterile. Third, cessation of ovulation is a pretty uniform feature of GVHD more severe than Grade II. Finally, people with Grade IV GVHD aren't likely to being having sex anyway; they're pretty sick and the vaginal mucosa is often affected (so it hurts).

The sponsor was unable to find a single case of a pregnancy occurring in a post-blood-and-marrow transplant patient with Grade-III or Grade-IV GVHD. Nevertheless, their liability lawyers insisted on a full treatment of the issue in the consent form.

7. Tube feeding a questionnaire

In this study, healthy volunteers received a precisely measured liquid meal inserted directly into their stomach for subsequent physiological measurements. The consent form included the sentence: "Study procedures will include the use of a nasogastric tube, for insertion of a liquid meal and questionnaires."

8. Consent cost vs payment contradiction

The consent form for this study included the following contradictory text (italics added):

> **COST TO YOU**
>
> *There is no cost to you for participating in this study.*
>
> **COMPENSATION FOR INJURY**
>
> If injury occurs, treatment will in most cases be available***.*** *If you have insurance, your insurance company may or may not pay these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed for these costs.* Funds to compensate for pain, expenses and other damages caused by injury are not routinely available.

9. Medical treatment after dying

The consent form for this study included the sentence, "Some people have died from serious allergic reactions. If this occurs, you will need immediate medical attention."

Conclusion

Informed consent forms address very serious matters, so they can be tedious to read. Nevertheless, the examples above are not an advisable way to lighten the mood.

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