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Informing vs. Persuading in the Consent Process

By Dennis J. Mazur and Norman M. Goldfarb

There is a fine line between informing a potential study participant about a clinical research study and improperly persuading him or her to participate in the study. According the Belmont Report, persuasion is not acceptable if it constitutes unjustifiable pressure:

> Unjustifiable pressures usually occur when persons in positions of authority or commanding influence — especially where possible sanctions are involved — urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

Similarly, the Council for International Organizations of Medical Sciences, in its International Ethical Guidelines for Biomedical Research Involving Human Subjects, states:

> The prospective subject must not be exposed to undue influence. The borderline between justifiable persuasion and undue influence is imprecise, however. The researcher should give *no unjustifiable assurances about the benefits, risks or inconveniences of the research*, for example, or induce a close relative or a community leader to influence a prospective subject's decision. *[italics added]*

Statements made in the informed consent form or verbally, during the informed consent discussion, should not cross the line into undue influence, especially when study participants bear a moderate to high risk in the study. This article draws the line on the basis that any influential statement beyond the content of the consent form is suspect.

This article focuses on statements, but undue influence involves not just what is said but who says it. Statements by a person in a position of authority or by a person who has power over a potential study participant are more likely to create undue influence.

The following 17 rules will help IRBs and investigators determine which statements are permissible information and which are impermissible persuasion.

Permissible Statements

1. Any statement approved by the IRB

   Example: Participation in this research study is completely voluntary on your part, and you may cease participation at any time.

2. Any statement that clarifies the consent text but does not, in other respects, make it more persuasive

   Example 1: A 50% chance of getting the study drug means you have a one in two chance of getting it.

   Example 2: The study sponsor will know you are participating in the study and will have access to your study records.

3. Any statement that provides additional detail to clarify the consent text

   Example: "Serious risk" includes the possibility of a long-term disability.

4. Any statement based on the Investigator's Brochure

   Example: In four previous studies, there were no deaths.

5. Any statement based on the consenter's qualified professional expertise, e.g., as a licensed physician

   Example 1: I think this study is a reasonable care option for you.

   Example 2: We might learn something that will help me treat you better after the study.

6. Any statement that the IRB would have approved for the consent form, leaving aside the question of brevity.

Impermissible Statements

7. Any statement that is more persuasive (in content or tone) than the consent text

   Example: There is a real chance that your health will improve in the study.

8. Any statement that advises or directs the patient to enroll in the study.

   Example: You should sign up for the study.

9. Any statement that calls attention disproportionately to a positive element of the consent text or downplays a negative element

   Example 1: Given your insurance coverage, getting a free MRI should not be discounted.

   Example 2: Given your good health, you should have no trouble in the study.

10. Any statement that redirects the patient's attention away from his or her concern

    Example: Yes, that's a risk, but let's talk about whether you can even participate in the study.

11. Any statement that responds to the patient's concern about his or her personal impact with an appeal to his or her altruism toward other patients, the consenter, the investigator, the research site, the study, the study sponsor, or the general public.

    Example 1: You realize, don't you, that the drug you are taking now was tested on other patients in previous clinical trials?

    Example 2: We need just one more patient for the study to meet our goal.

12. Any statement that attempts to minimize risk to study participants.

    Example: Serious injury is very unlikely in this study.

13. Any statement that suggests the study treatment will be effective.

    Example: In a previous study, the treatment appeared to be effective.

14. Any statement about who has already agreed to participate.

    Example: My sister is participating in this study.

15. Any statement of opinion that is not based on a solid foundation of facts, experience or expertise.

    Example: The head of our department strongly supports this study.

16. Any statement that is permitted by one of the above rules but is not permitted by another.

17. Any statement that the IRB would have not have approved for the consent form, leaving aside the question of brevity.

Because this list intentionally includes examples in the gray zone of permissibility, different IRBs could reach different conclusions about their classification. Wherever an IRB draws the line, it should apply it consistently. Readers are invited to contact the authors with their perspectives and other rules and examples of statements that can help draw the line between permissible and impermissible statements.

Authors

Dennis J. Mazur, MD, PhD, is the author of *Evaluating the Science and Ethics of Research on Humans: A Guide for IRB Members,* published by the Johns Hopkins University Press, Baltimore, Maryland, 2007. Contact him at mzrdj11@gmail.com.

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.

