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40 Techniques for Increasing the Likelihood of Obtaining Consent from a Study Participant

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The purpose of the informed consent process is to *inform*, not to *persuade.* A previous article in the Journal identified six types of informative statements that are permissible and 11 types of persuasive statements that are impermissible.[1]

The use of "undue" (i.e., excessive) influence is also prohibited. However, influence that is not "undue" is permitted, and can hardly be avoided. The line between acceptable and unacceptable influence can be unclear or disputed. For example, some human subjects protection professionals believe that a patient's primary care physician is the worst person to obtain consent because their relationship introduces undue influence into the informed consent discussion. Other human subjects protection professionals take the opposite view — that the primary care physician is the best person to obtain informed consent because he or she has the best understanding of the patient's health needs. Other clinical research professionals have intermediate views.

Numerous techniques can increase the probability of obtaining consent from a potential study participant. Most of the techniques presented in this article are drawn from two books written by Robert B. Cialdini, a social scientist who is the leading expert on persuasion and influence.[2,3] The principles, evidence and reasoning behind the various techniques are discussed in Dr. Cialdini's books.

The techniques in this article cover the range from ethical to unethical. The ethicality of a given technique should be assessed based on whether it assists a potential study participant in making a well-informed, objective and clear-headed decision about whether to participate. Readers will probably recognize the use of certain techniques in their current consent process and can evaluate the ethics of these techniques and take steps accordingly.

The most important aspect of the informed consent process is the potential study participant's trust in the integrity of the process and the good will of the person obtaining consent. This trust will be destroyed if the potential study participant senses — consciously or unconsciously — that he or she is being deceived, manipulated, disrespected or taken advantage of.

The use of unethical techniques in the consent process has consequences that go far beyond their impact on study participants. They also have corrosive impacts on the clinical research organization itself:

- An unethical culture creates "moral stress" for ethical employees, sapping their energy, undermining their performance, and deflating their commitment to the organization's goals. This effect applies to employees forced to violate their ethical principles and also to those who just observe unethical behaviors.
- An unethical culture drives out ethical employees, incurring substantial direct and indirect costs for the organization in securing and training replacements.
- The departure of ethical employees increases the concentration of unethical employees, who are likely to engage in other types of unethical behavior, ruining the organization's reputation with customers and suppliers, and cheating the organization itself. A destructive spiral can ensue.

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Preconditions to the Consent Process

Before attempting to obtain consent, a clinical research professional must be knowledgeable about the study and sincerely believe it is a valid option for consideration by a potential study participant. Further, the clinical research professional must sincerely believe that the informed consent process does justice to the potential study participant. Potential study participants will likely perceive — consciously or unconsciously — any wavering in these beliefs and therefore decline to give consent or give consent but later withdraw from the study.

At some point in the consent process, and preferably early in the process, the person obtaining consent should "know" the potential study participant. He or she should ascertain the person's motivations, knowledge of the clinical research process, and other characteristics that could bear on the informed consent process. For example, is the person's culture oriented to the individual or the community? Is the person's primary motivation to gain access to a new treatment, obtain routine care, help future patients, or generate income? Knowing the person is vital to many of the techniques described below.

Before accepting consent from a potential study participant, the person obtaining consent (and the principal investigator) must sincerely believe that the potential participant has chosen to participate in the study on his or her own volition, without manipulation, deception or the withholding of pertinent information.

Further, the person obtaining consent must sincerely believe that the potential study participant has a reasonably high probability of sticking to his or her decision during the course of the study. Any defect in the consent process might be revealed when a participant has second thoughts halfway through the study.

40 Techniques for Increasing the Likelihood of Obtaining Consent

Some of the following techniques channel the attention of potential study subjects or put them in a frame of mind that predisposes them to give consent, without providing information about the study. Others relate directly to the study. Others increase the likelihood that study subjects will not change their minds later. This is not a list of recommended techniques. Some of them are clearly ethical, others are clearly unethical, others are ethical if performed in an ethical manner, and others are subject to dispute.

1. **Put the person in a good mood.** Schedule consent visits on days with nice weather. (Good weather puts people in a positive frame of mind, but mentioning the good weather can cause them to make a mental adjustment that cancels the effect.) In the waiting room, provide reading materials that consist of stories that are warm, funny and have happy endings.
2. **Make the person feel welcome and important.** Greet him or her by name. Treat him or her as a VIP. Offer a hot drink (unless it is a hot day). Touch him or her on the shoulder or arm. Look into his or her eyes for two seconds. Make the room warm and welcoming (i.e., not a typical exam room). Paint the room in a warm color and light it sufficiently but not harshly.
3. **Create an environment that puts the person in the right frame of mind.** For example, if the person's likely objective is to generate income (e.g., in a healthy volunteer study), hang a poster on the wall that illustrates financial security or the good things in life that money can buy, without any reference to the study. If his or her likely motivation is to help future patients (e.g., in an advanced-cancer study), hang a poster on the wall that shows people that look like future patients.
4. **Create an environment and process consistent with the person's objectives.** For example, if the person wants treatment for his or her medical condition, wear a white

coat and use words like "patient" and "treatment," rather than "subject" and "experimental." (In other words, encourage the therapeutic misconception.)[4]

5. **Create a sense of obligation.** At the outset of the consent visit, give the person a flower or some other small gift, preferably related to health or the idea of good health. For example, give the person a flower and then, if he or she appreciates it, a second flower to surprise him or her and demonstrate generosity.
6. **Promote either a rational or intuitive decision process.** Encourage deliberate, rational and pragmatic analysis with words like think, objective, analyze, consider and facts. Encourage a quick, intuitive, emotional, idealistic process with background music and words like feel, intuition, sense and impression.
7. **Establish that you are not just *like* the person but a *member* of their group.** Find commonalities like a shared birthplace, neighborhood, ethnicity, age, hobby, previous job, or bus line. Use words like family, mother, home, community, we, us, and together.
8. **Demonstrate that you like the person and be likeable yourself.** Be friendly. Give compliments. People like people who like them.
9. **Synchronize with the person.** Mirror his or her speech patterns and body movements. Turn the pages of the consent form together. Play a game to "relax" the person that involves, for example, one person tapping on the table and then the other person reproducing the pattern.
10. **Demonstrate credibility.** Early in the discussion, identify a drawback of the study, followed immediately by a larger positive. For example, say, "This study will require three blood draws — not much fun, right? — but we can avoid biopsies."
11. **Communicate the necessity of a good decision process.** Make it clear that the person will not be accepted into the study unless he or she demonstrates an informed and well-considered decision.
12. **Approach the consent process as a mutual learning process.** Both participants should be on the same side of the table, both literally and figuratively, as they determine whether the person should participate in the study.
13. **Establish a mutually acceptable process.** Review the consent process with the person and obtain their agreement to it. Obtain conditional acceptance by asking, for example, "If we follow these steps, are you are comfortable at each step, do you think you will want to participate in the study?" The process should be expeditious but take long enough to give the person the sense that they have *invested* time in the study that that they do not want to waste.
14. **Ask the person questions.** Ask about the person's motivations and attributes. Ask them to explain in writing why they are interested in the study.
15. **Tailor the process to the person's motivations.** For someone who wants the safety of a group, emphasize that other people are participating in the study. For someone who wants to "make a difference," emphasize the importance of individual contributions.
16. **First offer a less appealing study.** If there is another study that would be less appealing to the person, briefly discuss that one before offering a more appealing study, making it more desirable by contrast.
17. **Ask the person if he or she has an attribute that supports participation.** For example, ask if he or she cares about other people. Or, ask if he or she supports medical science.
18. **Explain why the study appears to be a good fit for the person.** Reference their age, gender, health condition, quality-of-life goals, etc.
19. **Provide "social proof."** Describe how other, similar people are participating in the study.

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20. **Discuss whether participation by the person would be feasible.** For example, are there logistical obstacles to participation?
21. **Give the person options.** Let them tailor the study to their specific needs. For example, what are the most convenient times for study visits? What kind of visit reminders would he or she prefer?
22. **Ask the person for advice.** For example, ask which parts of the consent form could be clearer. Ask where to find more study participants. Ask whether you should schedule visits on Saturdays.
23. **Praise the person.** Say that he or she has a characteristic that promotes the consent process. For example, if the person is a bookkeeper, say, "I really admire the attention to detail that bookkeepers have." Or, if the person is a teacher, say, "Teachers teach, but they also have to be good learners."
24. **Use words that reinforce the person's positive traits and attitudes.** For example, if he or she want to help future patients, use words like kind, caring, thoughtful, considerate, nurture, protect, generous, comfort, nourish and noble.
25. **Focus the person's attention on their dissatisfactions.** For example, ask him or her if he or she is unhappy with his or her heath status as it relates to the study's therapeutic area.
26. **Focus the person's attention on a positive aspect of the study.** For example, say, "The important thing about this study is that the drug works in an entirely new way." Or better, pose the statement as a question, e.g., "Do you agree that having to take only one pill a day is a big advantage?" Or even better, ask, "What appeals to you about this study?" Guide the person into justifying their participation with a sentence in the form: "I want to participate in this study because…"
27. **Provide information in a form that is easy to process.** Refer to the study with a name that is easy to pronounce and easy to remember. Draft the consent form so it is easy to read and understand. Use lay language. Use an easy-to-read font. Use the person's first language. Avoid interruptions. Avoid visual or audio distractions.
28. **Use metaphors and similes.** For example, a healthy volunteer study might be like a job testing a video game. A vaccine study might be like gaining a superpower to fight disease.
29. **Give importance and credibility to the study.** Explain the importance of the study. Print the consent form on heavy paper and present it to the person in a leather folder. Cite credible and trustworthy authorities who have endorsed the study as consultants or investigators. Use your own credibility to endorse the study.
30. **Provide reasons and causality when making requests and giving explanations.** The word "because" makes statements sound logical and well reasoned, even if the connection to the reason is tenuous or nonsensical, because the word makes statements sound logical and well-reasoned.
31. **Characterize the time and discomfort of the study as an investment, not a cost.** For example, say, "This study will require a personal investment, not of money but of time. Are you comfortable making that investment?"
32. **Recommend the study.** Tell the person, "Based on [statements by the person], this study sounds like a good fit for you."
33. **Personally endorse the study.** Put your personal credibility behind the study. For example, say, "I would enroll my daughter in this study."
34. **Obtain the person's confirmation of consent in multiple ways.** In addition to a signature on the consent form, obtain his or her reasons for participating, both verbally and in writing. Give him or her the opportunity to volunteer to fill out a visit reminder

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card for the first visit, complete with a little drawing that says something about themselves (if appropriate).

35. **Draw out objections.** As the consent process progresses, ask the person, "How are we doing?" or "Do you see any problems?" Be prepared to address any issues or objections and then refocus the discussion.
36. **Make concessions.** For example, propose mid-morning visits and then accept visit times that better fit the person's work schedule.
37. **Move the person closer to the decision to participate in smooth, incremental steps.** Start with a question like, "How are you feeling today?" Follow with a series of steps that create consistent affirmative behavior, giving momentum towards a final "yes." Compliment their consistency and confirm progress as each step is made. For example, ask, "So you are comfortable with the risks in the study?" Break the consent document into sections and obtain the person's initials on one section at a time, in any convenient order. Each step should be a voluntary act of free will on the part of the person.
38. **Create a sense of urgency if an opportunity is not to be lost.** Tell the person the opportunity to participate is limited by time or scarcity, but do not rush their decision process.
39. **Just before completing the consent process, pause.** Once the person has made the decision to participate, create a sense of uncertainty as to whether they will be accepted into the study. Make them wait briefly before giving them the good news, to make the study seem more desirable. Then use words like "commitment" and "personal responsibility" and try to get them to use the words, as well.
40. **Obtain concurrence for the person's participation from his or her close supporters.** Include, as appropriate, the person's family member(s), caregiver(s) and physician(s).

Conclusion

The consent process begins with a person who knows little or nothing about a study and ends with a person who knows a lot about the study and who may or may not want to participate. The consent process should not consist of dumping a pile of information on someone and then asking for their decision. Rather, it should consist of an effective and considerate process that walks the person through a series of steps in which he or she digests and interprets the information and then makes a voluntary and informed decision about whether to participate based on his or her personal goals and situation.

Clinical research professionals can use numerous techniques to guide a potential study participant through the consent process. Because some of these techniques clearly work to the person's advantage, they can be considered ethical. Because other techniques clearly work to the site's advantage without regard to the person's interests, they can be considered unethical. The ethicality of other techniques may be debatable or depend on how and when they are used.

The advantages of an ethical consent process should not be subject to debate. Each site should satisfy itself that its informed consent process is legal, ethical by its own standards, acceptable to its study personnel, and compatible with the general consensus in the clinical research enterprise. An unethical process not only works to the disadvantage of study participants but also corrodes the culture and degrades the performance of the site.

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