

The Personal Side of Subject Recruitment

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Ethical practitioners of clinical research recruit subjects in a manner that protects the subjects' welfare and respects their rights. Numerous laws, regulations, guidelines and guidances set forth detailed requirements and prohibitions. Bioethicists and regulatory specialists interpret these rules, dissect the ambiguities, and tease out the implications. With diligent study, we can comply with the rules and ethically recruit subjects.

However, this mechanistic, rules-based approach to ethical conduct can lead us to lose sight of the forest for the trees. We can go astray when a situation arises that is not precisely covered by our personal version of the rule book. In a specific circumstance, our actions are not necessarily ethical just because we are following the rules. By relying on the rules and ignoring the underlying ethical principles, we can lose our moral compass.

In this article, we will discuss principles and methods for recruiting study subjects that are largely drawn from the world of marketing and sales. As with most fields of human endeavor, marketing and sales is rife with unethical behavior. However, there is no requirement that marketing and sales must be unethical. In fact, there are marketing and sales principles and methods that are both very effective and highly ethical. They are effective because they optimize interpersonal engagement and communications. They naturally generate ethical conduct because they align the interests of the recruiter with the interests of the subject.

What is a "Study Subject"?

The first principle of marketing and sales is to know your customer. Study subjects are not "customers," but, like customers, we engage them to obtain their agreement. If we are to deal ethically with study subjects, it is certainly appropriate to understand their motivations, concerns and situation. Unfortunately, the terminology we use to describe study subjects can limit our ability to deal with them ethically.

What should we call the people who participate in a clinical trial? Many of them are patients, but calling them "patients" promotes the therapeutic misconception that the study is primarily designed for their personal medical care. They are experimental subjects, but calling them "subjects" communicates that they are passive recipients of the study treatments. They are volunteers, but calling them "volunteers" suggests that they bear the burden for any unpleasantness that may occur. It may also flatter them into taking risks beyond what their personal welfare dictates. We can avoid this semantic baggage by calling them "participants," but at the cost of offering any guidance about their role in the study. (Investigators are also participants.) (In this article, based on common usage and clarity, we use the term "subject." We use it for both active and potential study participants. We use the term "he" for both male and female. We also refer to subject recruiting and obtaining informed consent collectively as subject recruiting.)

No perfect terminology exists, but all of the above terms have some merit. Each provides a perspective on the people who participate in a clinical trial. However, the terms tend to reduce them to a single dimension and discount the most important perspective – that people who participate in a clinical trial are, first and foremost, human beings. Further, they usually are not people in isolation; they are probably part of a network of relatives, friends, healthcare providers, spiritual advisors, etc. If we ignore their personal network – their

village – we see only part of the person and remain outsiders to their village. Without the support of their network, retention and adherence may be lower. Involving relatives, friends, physicians, etc. in the subject recruiting process simply recognizes the reality of their existence.

“Selling the Study”

When recruiting a subject for a clinical study, we must, of course, avoid coercion and undue influence. In other words, we can't twist their arm to participate in the study. Coercion and undue influence arise when we try to “sell the study” to a subject. However, there is an approach to selling that does not invite coercion and undue influence.

There are three main methods of selling:

In **transactional selling**, the focus is on the transaction at hand. Transaction selling works well with simple products, short selling cycles, and one-time customers. For example, if you pull into a gas station with a steaming radiator, the mechanic knows you will probably never return, no matter how good the service or reasonable the price. He has one chance to make a profit, so it is tempting to sell you a new radiator when the problem is only a loose hose.

In **relationship selling**, the focus is on the relationship. Relationship selling works well with complex products, long selling cycles, and repeat customers. For example, if you want to buy a sophisticated life insurance product, careful reading of various policies will probably shed little light on the right decision. You probably need a trustworthy expert to guide you to the right product. The insurance salesperson thus starts by selling himself as your trusted advisor. He talks about his many years in business, numerous satisfied clients, and mutual friends. He asks about your family, pets and hobbies, and remembers them! However, because he knows you have to trust him, it is tempting for him to sell you more insurance than you need or steer you to the product that pays the highest commissions.

In **consultative selling**, the focus is on helping the customer make the right decision for himself. Consultative selling works well if the customer wants assistance with the buying decision. For example, if you want to buy an automobile, a consultative salesperson will help you identify which criteria are most important to you and then give you objective information about them. If economical operation is important to you, he will tell you that replacement parts are expensive, without you having to ask. With this information, you may decide to not purchase the vehicle. Or, you may decide to incur the extra expense to avoid the risk of being tricked by a less-forthcoming salesperson.

While transactional and relationship selling are prone to manipulation, i.e., coercion and undue influence, consultative selling is not. If the consultative salesperson sincerely wants the customer to use his own judgment to make the right decision, manipulation cannot occur. There is no selling, or even persuasion, just the provision of useful facts and perspectives.

Consultative selling is the best way to develop a strong relationship with the potential customer because the customer can sense that the consultative salesperson is genuinely interested in his autonomy and welfare. It thus has similarities to relationship selling. However, differences between relationship and consultative selling include:

- The relationship salesperson asks about your hobbies to build a personal relationship. The consultative salesperson does not, because they are irrelevant to a professional relationship.
- The relationship salesperson asks the potential customer to trust him. The consultative salesperson asks the potential customer to trust himself.

- A good relationship salesperson should sincerely care about his customers, but he develops the relationship in order to make the sale. In consultative sales, causation is reversed: The consultative salesperson gains the relationship as a byproduct of helping the customer make the right decision.
- If a customer asks the relationship salesperson "what should I do?" he may respond, "as your friend, I advise you to buy the product." In contrast, the consultative salesperson will summarize the facts, offer to answer questions, and let the customer make the decision when he is ready to make it. The consultative salesperson does not give advice; he offers facts and perspectives. The difference between advice and perspective can be subtle. An example of advice is: "In my medical opinion, you should participate in this study." An example of perspective is: "In my medical opinion, you may benefit from this study."
- The relationship salesperson loses the relationship when he tries to sell the wrong product. In contrast, the consultative salesperson gains the relationship even when losing the sale.

Because consultative selling is relatively uncommon, it can make a strong impression on potential customers. It is especially effective in generating positive word of mouth. "Lost" customers may show up years later when they are ready to buy. Consultative selling is very effective over time but requires discipline when faced with a short-term sales goal.

Consultative selling is clearly the most ethical model for recruiting subjects. It works well for study coordinators who want to help people and are uncomfortable in the role of salesperson. It is more difficult for physicians because giving advice is a big part of their job.

Consultative selling has salutary affects on the salesperson's sense of personal integrity and job satisfaction. There is one requirement, however: the salesperson must believe in the products he is selling. If not, he cannot in good conscience advise anyone to buy them. If a study coordinator does not believe in a study, he will be a poor recruiter and probably experience a high rate of subject drop-out.

Features vs. Benefits

A common mistake in selling and marketing is to promote product features rather than the benefits they offer the customer. For example, when selling automobiles, instead of talking about engine displacement, talk about fast acceleration. However, it is usually not that simple. Some customers want a big engine for fast acceleration; others want to tow a trailer; others want a throaty roar; while others want to open the hood for their friends. The point is that the best way to know what benefit a feature provides is to ask the customer (and hope that the customer knows himself, and is willing to answer honestly). We disrespect a customer when we ignore his individuality.

When we recruit a subject into a study, we can talk about the potential health benefits for the subject and how his altruism will help other people with the same disease. We may mention extra medical care and a generous stipend. However, why not just ask the subject why he is interested in the study? Ask him about his concerns. By asking first, we may find out what he wants so we can address that benefit directly. We may find out that the subject's motivation is problematic, e.g., just for the stipend. We will certainly communicate to the subject that we care about him as a unique individual.

Before we even start to talk with a subject about a study, we must first open his mind to clinical trials in general. It is presumptuous to assume that the subject is interested in any study, much less ours. Why not take a few minutes and first ask him questions such as:

- Do you know anything about clinical research?

- Would you like to learn more?
- If you were to participate in a study, what would your motivation be?
- Can I tell you about a study that may interest you?

By starting with questions such as these, we begin to build trust. We can guide the conversation appropriately and save everyone time.

Satisfaction Guaranteed

Nordstrom, the department store chain, is famous for its customer service. The urban legend is that it once accepted the return of a used automobile tire, although it doesn't sell tires. Less well known is that if a customer sees an item he wants to purchase and tells the sales associate he saw it for less across the street, the sales associate is required by store policy to take the customer's word for it and match the lower price.

Nordstrom is not the only retailer that trusts its customers. Walk into your local Safeway grocery store. Pick up a cantaloupe and bring it to a cashier. Tell him that you bought a bad one yesterday. Ask for a free replacement. You'll probably get your free cantaloupe, with a smile. (Store personnel are required to smile.) Can't find the cantaloupes? Ask a stock clerk, and he will probably stop what he is doing and walk you over to them. That is also store policy.

These retailers and many others trust their customers enough to offer a satisfaction guarantee. Although some customers take unfair advantage, the losses are more than covered by revenue growth from loyal customers and positive word-of-mouth. Because these retailers trust their customers, their customers know they can trust these retailers.

Most research sites endeavor to keep their study subjects satisfied. After all, if they are not satisfied, they may miss study visits, skip medication doses, and leave the study early. However, if we think of them as trusted partners, we can do more. For example, we can ask a few potential subjects to review the informed consent form before it is finalized. We can give them the opportunity to assess their own comprehension of the informed consent information. We can give them a form for anonymous feedback after every study visit. We can keep them informed about the progress of the study. By thinking of them as "partners" rather than "subjects," we generate mutual trust and more successful studies.

At the end of a study, we want every subject to say: "I made the right decision for me, and I would make the same decision again. When is our next study? Can I tell my friends?"

Recruiting a subject for a study can be a major accomplishment, but it probably will not make the study coordinator's life significantly better. In contrast, building an ongoing relationship with ten subjects over ten studies can make it significantly better.

Interpersonal Communications during the Initial Visit

During the initial visit, our objective is to help the subject make the right decision. We do not want to manipulate him, but neither do we want to throw up roadblocks to a constructive interaction. We want to open the communication channels as wide as possible. Participating in a clinical study is an important, perhaps life or death decision, so we want to provide an environment that minimizes distraction and allows the subject to make a thoughtful decision. We want our skill in interpersonal communications to facilitate – but not manipulate – that decision.

If you are not already comfortable with the techniques described below, practice them until they become natural; the subjects will detect any artificiality. While these techniques are

broadly applicable, they do not apply 100% of the time, so use your judgment and adapt as appropriate.

As mentioned above, we cannot in good conscience help a subject enroll in a study that we, ourselves, do not believe in. If we believe in a study and that it would be a reasonable decision for the subject to enroll, he will gain confidence from our positive attitude. There is no need to say, "This is a great study for you."

You want to put the subject at ease so he can focus on the decision. It is essential to be sincere, honest and genuine. You probably cannot fake sincerity. People like people who like them. If you do not inherently like people, study coordination is probably not the job for you. Show that you like the subject by being warm, friendly and attentive. The subject wants you to respect him and probably also wants to respect you. Use your knowledge about the study and clinical research in general to earn his respect. By demonstrating confidence in your knowledge and your ability to conduct the visit, you will reinforce that respect and create trust.

There are many ways to disrupt this new relationship: hesitate; evade questions; say something thoughtless; come on too strong; act in a patronizing manner; show embarrassment; exhibit stress, nervousness or distraction; etc. The techniques described here will help you avoid these behaviors. Begin by putting your other priorities aside, relaxing, being comfortable with yourself, focusing on the subject, and taking your time.

Most people are comfortable with people who are similar to themselves. Therefore, emphasize, but do not force the similarities between you and the subject.

Frequent smiles and nods will engage the subject. Your smiles will appear unnatural unless you mean them. Any stress or discomfort will make genuine smiles very difficult. Project warmth, friendliness and likability, but not inappropriate intimacy. Watch the subject for signs of discomfort, stress or hostility, such as squirming, fidgeting, crossing of arms, head shaking, looking away, and problematic facial expressions. If you detect a problem, fix the problem or ask the subject if there is a problem.

Speak at a moderate volume and act naturally. Modulate the volume and frequency of your voice. Your posture should be upright, not bent under your heavy burdens. Move with energy and confidence, but do not rush. Shake hands firmly, with a grasp that is neither limp nor overpowering. Note, however, that handshakes vary substantially across cultures, so adjust accordingly. When sitting down, lower yourself in a controlled manner; do not plop or crash into the chair. Assume a confident, open, upright posture. Show interest by leaning forward a bit with arms and legs uncrossed. If possible, avoid desks or other barriers between you and the subject. Sit directly facing him or at a small angle. At minimum, your face and preferably shoulders should be head-on. Personal boundaries vary by culture, gender and status, so be sensitive to the other person's movements and reactions. As the conversation becomes more relaxed, you can cross your legs, especially to mirror theirs. Use natural, spontaneous gestures to engage the subject and show energy and enthusiasm.

Be attentive. Nod occasionally to indicate that you are hearing what the subject is saying. Do not interrupt. Smile when he is finished. Pause before answering to show that you have given his question serious thought. Answer directly, clearly and deliberately. If the answer requires elaboration, start with the short direct answer and then elaborate: "Yes, let me explain..."

When the subject says something positive, repeat and affirm it. When he asks a question or raises an issue, it probably means he is interested in the study and wants you to help him resolve the issue. If he is not interested, he probably will not bother. Wait for him to finish speaking; then rephrase the question or issue to communicate that you heard it. Express your understanding and perhaps sympathy; then respond with conviction, leaning forward

and maintaining eye contact. Even if the question is difficult or confrontational, stay calm and relaxed. Respond to the information in the subject's statement, not to the manner of delivery.

You will undermine your authority and likability if you say anything negative, especially about the study, your organization, the subject, or yourself. Talk about challenges, not problems. However, do not gloss over the challenges or set false expectations; they will probably cause trouble down the road. For example, if the investigator is sometimes late for study visits, say so up front. If there is going to be discomfort, do not minimize it. People are tired of all the routine deceptions of modern life; they will be pleasantly surprised by your honesty. Trust them to make the right decision for themselves.

If the subject arrives with a relative or other companion, include everyone in the conversation. Treat everyone with equal respect. Do not side with one person against the other. When it comes time to obtain the subject's signature on the informed consent form, there is no reason why you cannot obtain the signature of everyone in the room. They all play a role in the subject's participation, so why not obtain their commitments as well?

When reading from the informed consent form, pause frequently to make eye contact with the subject. When it is time to give him the document, tell him what you are doing so he won't be puzzled or surprised; then hand it to him as the valuable document that it is. Do not thrust it at him or toss it on the table.

Your informed consent process may be for the subject to take the informed consent form home for reflection. If not, it is time for him to sign it (or not). He may hesitate. Ask him once if he has any further questions. Make the mechanics of signing easy and then get out of his way. If he needs a pen, hand it to him so he does not have to turn it around. Sit upright, sustain eye contact, and remain silent until he signs the form or says something. Do not break the silence with a joke, small talk, or more information.

After the subject signs the informed consent form, smile, nod and say something supportive, but not too enthusiastic. He has made his decision, so do not give him a reason to start rethinking it. Do not grab the signed form; leave it on the table for awhile. If he hands it to you, take it with care and place it carefully on the table before picking it up again. Sit back. Relax. Smile. Discuss next steps calmly and positively. Congratulate yourself – you have successfully helped the subject make the right decision for himself.

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