

Consent is agreement.

Informed consent is an agreement based on having sufficient information given and considered by a competent and capable person.

Voluntary informed consent is an informed agreement made by a person who has the ability to agree without any force, fraud, coercion or undue influence.

A consent form is a document that can be used before a jury to show that a person signed a form; it does not demonstrate informed consent.

RECRUITMENT PHASE OF THE CONSENT PROCESS

Advertising: Make an honest first impression. Regardless of what is said later, first impressions are lasting. An advertisement that cheers the experimental treatment as a breakthrough may set expectations that cannot be met. All recruitment materials must be reviewed and approved by an IRB. (See 3.4.2.A. for more on Advertising.)

Scripts: Advertisements often lead to a phone call to a call center or an office. The way that the phone is answered also sets a tone and can bias the information being heard. A script or set of talking points is recommended.

Websites that give information about the study are subject to IRB review.

CONSENT

Studies vary greatly in their needs. The process leading to completion of a quality of life questionnaire is far different from that needed for taking an experimental drug. When thinking about consent procedures, there are some leading questions.

1. What is the first information the person has about your study?
 - Is it clear that it is investigational/experimental/research?
 - If any promises are made are they valid?
2. Is the person competent to consent?
 - Is the person of legal age in your jurisdiction?
 - Has the person's ability to consent been compromised legally, mentally or emotionally?
 - Are there adequate support mechanisms? (time, pictures, advocate, etc.)
3. Is the person in a "vulnerable" situation or class?
 - Is the potential subject a minor, pregnant woman, or prisoner?
 - Does the potential subject have other therapeutic options?
 - Are those options available?

- Is the person dependent on the investigator or staff?
 - Is the person fluent in English? If not, what is the primary language?
 - Is the person literate in English? Not literate at all or not in English?
4. Is the consenting process conducive to informed consent?
- Is there time for the person to talk to a loved one or trusted resource?
 - Is the person presenting the consent information knowledgeable?
 - Is the person presenting the consent information an authority figure?
 - Is there adequate privacy?
 - Are there sufficient supplemental resources (e.g. pictures, models, etc.)?
 - If the targeted population is vulnerable, are there methods used to enhance their autonomy?
5. Is the timing appropriate in relation to the procedures?
- Is it before the protocol screening procedures?
 - Is it before any washout?
 - Has the person been put in a position where refusing will cause rescheduling or other inconvenience? Would refusal be conspicuous?
6. Is the consent form appropriate?
- Is it complete - all elements?
 - Is the reading level appropriate to a person reading at about the 30th percent of the target population
 - Is the format visually pleasing?
 - Is there an office procedure to assure that only the approved version can be used?
7. Is comprehension tested?
- Are the test questions verbal or written?
 - Are they open-ended or closed ended?.

CONTINUING CONSENT

Just because a person agreed at one point in time, there is no assurance that he or she will remember the information, still comprehend the information, or still want to participate. Continuing consent is critical. Selfishly, it can result in better compliance and fewer subjects lost to follow-up.

A prospective plan to re-confirm understanding and agreement is rare but wonderful.

MONITORING OF CONSENT

21 CFR 56.109(c)

"An IRB shall ... have authority to observe or have a third party oversee the consent process and the research."

IRC reserves the right to visit and to speak with subjects and to observe the consent process.

