

In the 1970's a friend challenged me. "What," she asked, "is the point of the consent form?" I replied, "Why it protects subjects, of course." She then asked, "If this document protects subjects, why doesn't the investigator sign it and give it to the subject?"

Documentation of consent is simply the proof that the elements were presented and that agreement was, at one point in time, given. Obtaining a signature from a subject and filing the form away provides a monitor and a defense attorney with "proof" of consent.

The consent document should be more than simple documentation. It can be used to assist the discussion, to provide a framework. It can assist compliance by acting as a memory tool. A well-tutored participant who knows what is to be expected will know what is unexpected and can better cooperate.

TITLE

The document is a consent form; it is not "Informed Consent." There is no rule that requires the study title; if used, it should be helpful. Specific identifying information such as protocol number and version can be in the footer.

LENGTH

The longer the consent form, the less likely it will be read thoroughly. This is the eternal tightrope we walk between inclusion of all possible information and possible comprehension. Judicious editing can often shorten a document considerably.

PERSONAL

As the purpose of a consent form is to transmit information from researchers to potential subjects, it should be in second person either singular or plural. That is, "I (the authority figure) am telling you (the potential subject) information. At the end, there may be a request to have the person sign if they consent,

ORGANIZATION

Consent forms should be organized so that they make sense. This may require reordering the elements. The logic should progress in much the same way that a discussion would.

For instance:

- Introduction to what this form is about
- We are conducting a study.
- This is what it is all about. The information being sought will fill what gap in knowledge?
- You are being invited for some reason
- If you agree, here is what will occur, how long it will take and where it will all happen.
- There might be some down-side to participation such as problems physically, financially, to your privacy, or emotionally. Oh, and if some harm does befall you, here is our plan.
- On the other hand, there might also be some benefits to you or to others.

- Of course, you have other options such as...
- You might have questions now or later so here are some names and numbers.
- You should know about your rights. You don't have to do this. Even if you do, you can drop out. In neither case will there be any penalty. Take your time and think about this.
- If you want to agree, please sign below.

FORMAT

Why do most consent forms resemble mortgage papers more than 8th grade textbooks? Why are there so few pictures, sketches, and diagrams in consent forms? A picture of a device can often save tortured explanations.

Why do so many large firms, with communications specialists, never involve them in consent form writing?

Why do all journals, magazine and textbooks have 2 or 3 columns and consent forms have one?

Different kinds of studies might merit other styles. A letter might be sufficient. A cover page to a questionnaire (similar to the cover to the college board tests) might work.

READING LEVEL

The consent form should be written to a level appropriate for the intended population. As a goal it should be targeted at the person in the 25th percentile of reading ability within that target population.

- If the population is all graduate students, the reading level should be college level.
- If the population is all 8th graders, the reading level should be about 6th grade, depending upon the school district.

Have a non-medical person (a neighbor? A teacher?) review the form before submission. Have them tell you what it said.

STAMPED DOCUMENTS

There is NO requirement that consent documents be stamped!
A date or version number in the footer works equally well.
Document control at the performance site is crucial.

AUTHORSHIP

The investigator must be happy with the content and style of the consent document.

The sponsor often includes a suggested format, template or language. Experienced sponsors recognize that the suggestion is just that. Sponsors – who have legal exposure – must be satisfied that all of the elements and the reasonably foreseeable risks, are all included.

IRBs have the authority to approve consent forms.

FDA does not pre-review drug study consent documents but IDE submissions must have the consent form included. The FDA does not, however, grant approval; it checks that the elements and the relevant risks are present and recognizes that changes will be made by the reviewing IRBs.

All parties often have input into the document which often creates a document by committee that is not readable. An editor is often recommended.

FURTHER CONSENT FORM HINTS

1. Use consistent personal pronouns throughout. Second person is preferred. The idea is: I/We are telling you (the potential subject) the information you need to decide.
2. Eliminate the witness line unless it is required. If included, define the task of the witness.
3. Add a line for the signature of the person gaining consent. This is an exchange of information and both parties should put their name on the line.
4. Do not imply that signing the form signifies understanding. Certifying to understanding does not assure it. Deleting "I understand that. . ." will usually leave a declarative sentence.
5. Use small paragraphs. Large, dense paragraphs are more difficult to scan. Lists are useful especially in the risk section.
6. Outline it first. The risks should be grouped together.
7. Use a header or footer. Number every page. Use a version number or version date.
8. If there are supplements such as timelines, lists of symptoms or contraindicated drugs, charts, HIPAA authorization or the Bill of Rights, the consent form should clearly refer to them.
9. If it must be stamped.... Leave space in the footer.

