Some Dos and Don’ts in drafting Informed Consent forms


DON’T use jargon.

DO use a serif font, such as Times or New York, and make it at least 12 points (bigger if you are enrolling elderly or others who might have difficulty seeing)! Serif fonts are easier to read than sans-serif fonts (such as arial, much less arial narrow!) which tend to blend letters and are harder on the eyes.

DON’T right-justify text… this unevenly spaces out words and is harder on the eyes.

DO use the word study instead of research or (especially) experiment. A study in the ‘90s showed that people hold more positive views of studies and are suspect of experiments.

DON’T use redundant language, such as “research study”.

DO use sentences that have one subject or topic/focus.

DON’T use run-on sentences.

DO use paragraphs that narrowly address the topic of the section heading; short paragraphs with very specific subjects are good, especially when introduced with a specific heading.

DON’T ever say “I understand that…” This language can be deleted with no loss of meaning. Any assertions about understanding are problematic, in that subjects cannot be charged with knowing what they do not understand.

DO use declaratory statement headings that summarize the main message of a section/paragraph, e.g., You have the right to withdraw, that is more fully explained by the following text. Note that many (too many, IMHO) institutions use (that is, IRBs require) a Q&A format; this requires a higher level of cognitive functioning to understand, given that one has to read the question, interpret it, then read the text and interpret how that answers the question. Better it is to state succinctly what it is most important for a potential subject to know, and then repeat that with more details.
DON’T use passive language; replace “study doctor” by “we”; replace “patients” by “subjects” or, when discussing what potential subjects can expect in the study, “you”.

DO say “take part” or “be” instead of “participate”.

DON’T unnecessarily repeat technical matters; try to figure out how to be efficient with the goal of enabling potential subjects to follow along. You don’t want their eyes to glaze over.

DO think about how you would verbally tell an 8 year old child what it is you are doing. Consent forms are supposed to be written at a 6th to 8th grade level, and this can be quite challenging to achieve (but it is doable). If you have an 8 year old, let them read your form. More importantly, getting the prose to sound normal, as if you were saying it, may help people follow along and ultimately understand.

DON’T isolate the risks by treatment arm (although your IRB may have a different approach to this), as it may yield unnecessary repetition and it risks unblinding subjects if some risks are unique to a blinded intervention.

DO try to put the risks in context, such as by categorizing as expected but minor, less frequent but severe, rare but serious, including possible death. Of course, if there’s one that’s likely and serious, that might be first in the list. And, don’t obfuscate important information by burying it in . . . noise.

DON’T capitulate to your IRB, or blindly adopt their consent boilerplate! IRBs tend to be conservative, they may not understand precisely what you are doing (at least not as well as you), and they may ask or require you to do things that you do not believe to be right. Learn the rules, check the literature, and use disagreements as opportunities to educate the IRB and learn the right ways to do things. Boilerplate language is often incoherent, so read things carefully to make sure the consent form makes sense and applies to your study.

DO take a look at the slides of a talk I’ve prepared on compensating subjects for research participation, which addresses the models and justifications for payment. This may give you some ideas about paying subjects. The file is on dropbox: Merz.talk about paying subjects.pdf

Good luck! Any questions, feel free to email me: merz@mail.med.upenn.edu