

## Informed Consent Form Makeover

By Norman M. Goldfarb and William DuBay

The typical informed consent form (ICF) now consists of perhaps ten pages of dense legal and medical prose. In a simplified and abbreviated form, it would look perfectly natural as the fine print on the back of an automobile loan contract. It's easy to criticize, but what *should* a 21<sup>st</sup>-century ICF look like?

- It should inform the subject, the subject's advisors, the investigator, study personnel, referring physicians, and anyone else associated with the study.
- It should comply with regulatory and legal requirements.
- It should be written in plain language, preferably at the 7<sup>th</sup>-grade level.
- It should help establish a constructive relationship between investigator and subject.
- It should not employ unnatural forces of persuasion nor cast gratuitous gloom on the study.
- It should hold the potential subject's attention.
- It should exclude extraneous rubbish.
- It should empower the potential subject to obtain additional necessary information and confirm his or her own comprehension.
- It should serve as a reference document as the study proceeds.

"An honest tale speeds best  
being plainly told."

—William Shakespeare

The ultimate test of an informed consent form is whether or not, at the end of the study, regardless of the outcome, the subject can say "I was fully informed and certainly not misled in any way."

### The Makeover

Are these objectives realistic? To find out, we performed a makeover on a mock ICF for the hypothetical HeadStart Pharmaceuticals' PepperPatch hair growing treatment. The Before-ICF is at [http://www.firstclinical.com/journal/2006/0605\\_ICF\\_Before.pdf](http://www.firstclinical.com/journal/2006/0605_ICF_Before.pdf). The After-ICF is at [http://www.firstclinical.com/journal/2006/0605\\_ICF\\_After.pdf](http://www.firstclinical.com/journal/2006/0605_ICF_After.pdf).

We invite you to judge the results for yourself.

Caveats:

- Neither the before nor the after forms are meant to be ideal informed consent forms. Rather, they are meant to illustrate principals of informed consent form design.
- The forms have not been tested for effectiveness, so the changes may or may not accomplish the above objectives.

Because of the use of a 14-point font and liberal use of white space and graphics, page count increased from 6 to 11. Shorter forms are preferable, but if shortness is the only design objective, a single page using 4-point font will suffice.

Changes from the before to the after form:

- The reading grade level decreased from 10.7 to 5.4. A reading grade level of 10.7 is typical of current ICFs, and better than many. Part of this decrease is due to the addition of short pieces of text at the top and bottom of the pages. Removing these pieces yields a reading grade level of 6.6. (Reading grade level scores are approximate.)
- The number of words in the form increased slightly, from 2021 to 2078. However, the use of words changed substantially: Streamlining the original text reduced word count; adding new content such as a quiz and interactive elements increased it.
- Not only is the text easier to read, but the contents are more useful. For example, risk probabilities are quantified. If the risk probability is unknown, the form says so. The right to litigate is clearly stated.
- Where possible, text is in two columns to aid readability.
- Color elements help the reader's eye move through the form. The colors are bright but somewhat subdued to avoid invoking inappropriate emotional reactions. Color is used moderately so the form can be printed on a desktop inkjet printer and also works in black and white. It is easy to differentiate the color original from black and white copies.
- Photos humanize the study and aid comprehension, especially for an audience that reads at a 7<sup>th</sup>-grade level. Along with the graphic design and use of color, they break up the text into digestible pieces and draw attention to the content.
- The subject signature block has been moved from the last page to the first page to minimize the incidence of missing signatures. Checkboxes are provided for each statement to which the potential subject is agreeing, to encourage him/her to read each statement (and avoid later legal claims). Similarly, the place where the potential subject initials each page is identified with a graphical element and states, "I have read this page."
- A place is provided on each page for the potential subject to write in any questions, and confirm that the questions have been answered. Writing on the form is encouraged to increase interactivity for active learning and demonstrate that the potential subject engaged with the form. A statement on the first page avoids potential legal problems that may occur if the potential subject attempts to modify the content of the form.
- Key information is presented with graphical emphasis, or multiple times, to reinforce comprehension.
- Most pages include a rhetorical question about the previous page to encourage careful reading.
- A short quiz on the next-to-last page helps determine whether the potential subject understood the form's contents (and avoids later legal claims). It may cause the subject to reread parts of the form. The open-ended questions minimize the scoring problems associated with guessing the answers to true/false and multiple-choice questions. If the potential subject misses one question, the person obtaining consent can review that point and probe into comprehension of other points. If the potential subject misses multiple questions, there may be a motivation or literacy problem that requires a more significant remedy.
- Several of the above items increase the interactivity of the form to increase attention and improve comprehension.

We invite readers to send comments and suggestions to [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).

**Authors**

Norman M. Goldfarb is Managing Member of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com). William DuBay is a readability and plain language consultant. Contact him at 1.949.631.3309 or [bdubay\\_92627@yahoo.com](mailto:bdubay_92627@yahoo.com).