

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

208. What matters to you?

The primary objective of the informed consent process is to ensure that the potential study participant *understands* the information so he or she can *give* (or not give) informed consent. The secondary objective is to ensure that the potential study *remembers* the information so he or she can *maintain* informed consent. As a practical matter, it is very difficult to digest — and even more difficult to remember — a long, complex informed consent form. The consent discussion is useful to the extent that it helps the potential study digest and remember the information that is important to him or her. This information can vary for each person. For example, one person might care most about one of the risks, while another cares most about the visit schedule. Rather than trying to force-feed potential study participants with all the information that *might* be of interest, the consent process should be structured to help the potential study participant digest and remember the information that matters to him or her. For example, the study participant could highlight or underline the most important bits of the consent form, a "kinetic" learning activity that can aid the processing of information. What am I missing here?

Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to ngoldfarb@firstclinical.com.

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