JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 4, No. 12, December 2008 "Can You Handle the Truth?"

The Informed Consent Decision Process

By Norman M. Goldfarb

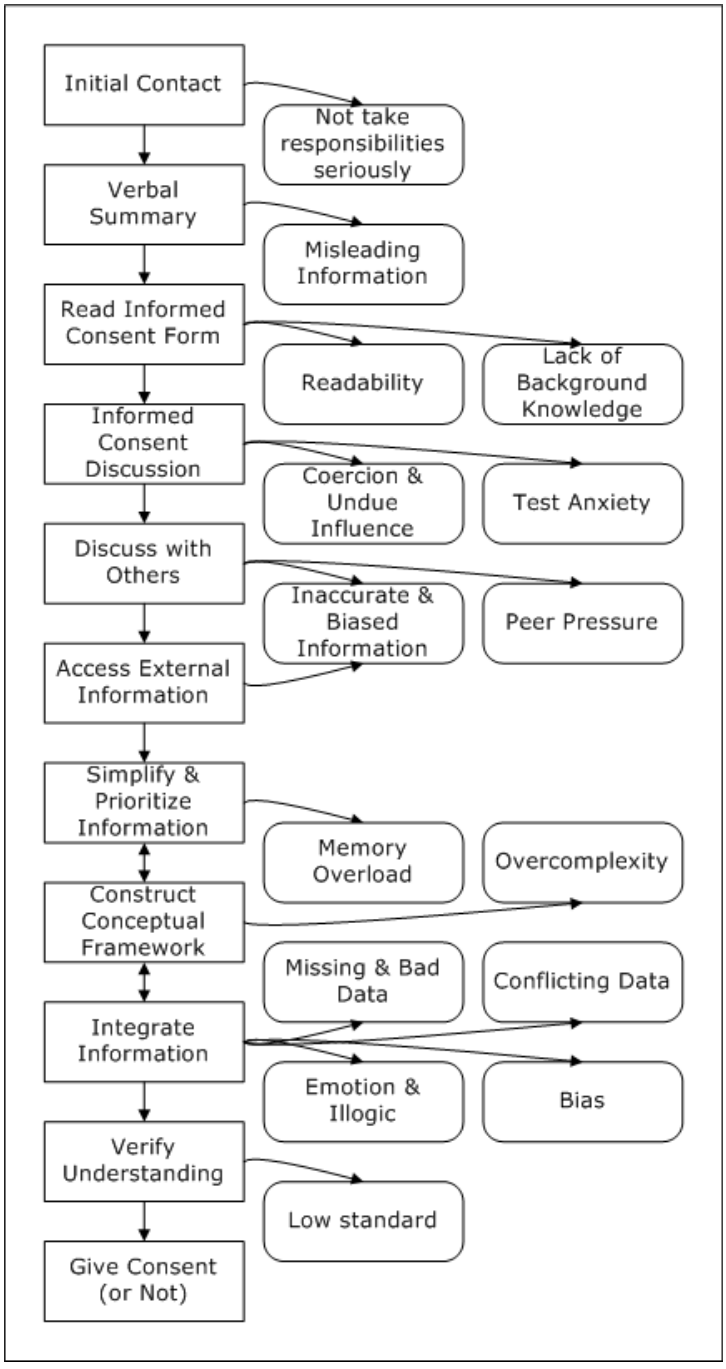
When we invite potential study subjects to participate in a clinical trial, we are asking for a significant investment in brainpower. Making an informed and thoughtful decision to participate in a clinical study is a lot more complicated than just reading a document, chatting with the investigator, and signing on the bottom line. Because it is probably the first time they are making such a decision, they do not even have the advantage of experience.

Figure 1 shows a somewhat-simplified version of the cognitive process of making the decision, with some of the associated challenges.

Most of the flowchart is self-explanatory, but an important section in the middle may need explanation. The arrows between "Simplify & Prioritize Information," "Construct Conceptual Framework," and "Integrate Information" have arrows on both ends because these tasks are done simultaneously.

The conceptual framework is like the storage racks in an auto parts store. Imagine you are starting an auto parts store. A truck arrives with parts of all sizes and shapes: gas caps, radiator hoses, engines, fuses, etc. The truck also delivers a flexible shelving system. Your task now is to assemble the storage racks and load them with parts. Should you put all the engine parts in one

Figure 1. Informed Consent Decision Process



© 2008 First Clinical Research and the Author(s)

area, or should the spark plugs go with the fuses and other electrical parts? Should the most popular parts go in the front, or maybe the smallest parts? If there is not enough room for everything, is it better to cram all the parts on the shelves, or store some of them in your garage? When your garage overflows, maybe the rest just gets tossed out.

Potential subjects have a similar problem with the informed consent information that also usually arrives in a big pile. Most people probably put the possible medical benefits, important risks, and unpleasant procedures in the front of the cognitive framework. Minor and unlikely risks go in the back. Or, perhaps all the risks and benefits go on one side. Visits might go on the top. There is probably way too much information to remember, so a lot gets left in the boxes or ends up in the trash.

Given the challenge of completing all the steps in the process, it is no surprise that many subjects rely on shortcuts, such as trusting the investigator or focusing on the possible medical benefits. By understanding the steps in the decision process, we can design an informed consent process that minimizes the obstacles. For example, we can help potential subjects construct their conceptual framework, prioritize their concerns, and integrate the information e.g., risks vs. benefits.

Author

Norman M. Goldfarb is Managing Director 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.

© 2008 First Clinical Research and the Author(s)