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The Three-Page Informed Consent Form

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Clinical researchers have a fundamental responsibility to ensure that subjects give informed consent to study participation. We provide the necessary information in a process that includes two primary elements:

- The informed consent form
- The informed consent discussion

Many informed consent forms fail to serve their purpose because they are way too long. An outside observer might conclude that they are intentionally designed to conceal information in a mass of mind-numbing text of little or no interest to the potential subject. As it turns out, there is a simple solution: Give potential subjects more control over the information they receive by moving most of the details to a supplemental document, where they are available as needed. We need to stop thinking of study subjects as *foie gras* geese who must be force-fed more information than they want. The geese do not appreciate it and neither do the study subjects.

Consent forms are not bloated to serve the endless curiosity of study subjects, but to serve the interests of sites and sponsors terrified of potential lawsuits. Lawsuits are a legitimate concern, at least in the U.S., but it would be easy for an injured subject to tell the jury that the consent form was too long to read and understand, thus defeating the informed consent requirement. The plaintiff's attorney can just ask the members of the jury to read the consent form and judge for themselves.

For most studies, the essential information (including the essential and additional elements required by regulation) might be summarized in as few as three pages so potential study subjects can focus on the most important points. Detailed discussions of the following topics can be relocated to a separate study handbook (with ample references from the consent form):

- The disease or indication
- How the drug (or device) works
- Rare medical risks
- Medical risks for standard-of-care procedures not specific to the test article
- Visit schedule
- Study procedures and tests
- Medication schedule and other at-home activities
- Lab specimens
- Alternative, adjunctive and standard-of-care treatments

The study handbook can be designed as a reference manual for continued use. For example, the visit schedule section could include a detailed calendar and list the procedures that will be performed at each visit. Different sections could apply to different groups of subjects, e.g., based on gender, age or concomitant medical condition. This approach would work even better with an online consenting process.[1]

Making consent forms longer and longer is clearly the wrong road to take. Stripping out material raises other issues. The study handbook system proposed here offers the best of both worlds. It is easy to look back at Tuskegee, Willowbrook and other grossly unethical

studies with disdain for the dismal ethics of the past, but how will the future look back at us with our encyclopedic consent forms?

Reference

1. “Making Informed Consent Work for All,” Susan Brink, Journal of Clinical Research Best Practices, December 2006

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