**INFORMED CONSENT OR INTUITIVE CONSENT?**

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How do patients decide to become subjects? The informed consent process assumes that if patients are given readable consent forms they will better understand clinical trials and make more informed decisions. To meet that assumption, Federal regulators and IRBs often (unrealistically) require consent forms to be written at a 6th-8th grade reading level. Although consent forms at that level should be easier to read and understand, Hochhauser’s 2004 review (Applied Clinical Trials, April 2004) of this research did not find much improvement in understanding with easier-to-read consent forms.

Emanuel and Flory reviewed 27 articles (JAMA, October 2004) using a variety of interventions thought to improve consent form understanding. But most interventions had relatively little impact on how well patients understood consent forms, mostly because different studies used different methods and comprehension measures, making direct comparisons almost impossible. Almost all the studies had serious psychometric problems with validity and reliability of the comprehension measures, as well as the use of true-false tests (where subjects can get 50% correct by guessing), or multiple-choice tests with similar problems.

Subjects got an average of 50+% correct responses. That suggests that they not only didn’t understand very much about clinical trials, but also were unaware of how much they didn’t understand. If they understood 54% of the information, did they not understand the other 46%? If they’re not aware of their ignorance, how can they sign a consent form that says: “I have read and understood…” a phrasing that the FDA rightly frowns upon.

How many patients refuse to be in clinical trials because they don’t know what they don’t know? Such statistics have not been published, but research finds some patients admitting that they’ve signed consent forms without reading them. Perhaps they trust completely in their doctor’s “recommendation” or perhaps they used other strategies to make their decision. Such findings suggest that decisions to be in a clinical trial (or not to be) are not always based on an adequate understanding of that trial. So how can patients so confidently reach a decision with so little understanding?

**Intuitive consent?**
Although Federal regulations, the Nuremberg Code, Helsinki Declaration and Belmont Report all emphasize the need for rational analysis of the informed consent process by prospective subjects, current research suggests that “intuition” may play a major role in how patients arrive at their “informed” decision.
Sharp found typical oncology consent forms included 14 topics, averaged 11 pages, and 2,700 words—not including HIPAA (American Journal of Clinical Oncology, December 2004). Some were over 6,000 words long. Given that people’s working memory can hold only three-to-five pieces of information at one time, how can patients cognitively process all the verbal and written consent information to make “rational” decisions? They can’t. So they must use some other cognitive strategy—such as intuition—to arrive at a decision.

Intuition isn’t what you probably think it is. It is not some kind of psychic ability that allows some people to know things that other people don’t know. A dictionary definition is: direct perception of truth or fact independent of any reasoning process. In other words, knowledge without reasoning. How can this be? Intuition is a way to process complex information by selectively focusing—usually unconsciously—on specific aspects of an experience. Patients may be unconsciously aware of the investigator’s demeanor, tone of voice, attitude, or other features that allow them to make decisions independently of the consent form process and consent form. Not only do patients not always attend to what investigators think they should attend to, but patients may be attending unconsciously to other aspects of the consent process.

In “blink. The Power of Thinking Without Thinking “ (2005), Malcolm Gladwell describes how people use “thin slicing” to extract relevant information from all the information around them. In “Intuition” (2002) Psychologist David Myers describes “knowing without awareness”—how people can know things automatically (unconsciously) or cognitively (consciously), noting Seymour Epstein’s description of experiential knowing (intuitive, automatic and nonverbal) or rational knowing (rational, analytic, verbal).

In medical treatments, Ubel and Loewenstein, (Social Science and Medicine, 1997, 44(5)) reviewed decision making and informed consent as affected by intuition and systematicity (more formal decision analysis strategy). They concluded that there was no best strategy for decisions based on patient values; some treatments might favor a systematic strategy, others an intuitive strategy. Despite the recognition of intuition as a valid way to make health care decisions, intuition has not yet been considered as part of the clinical trial consent process.

The Brain and Informed Consent
The emerging field of neurophilosophy deals with how the brain sciences interact with philosophy, including the area of neuroethics (e.g., Patricia Churchland’s (2002) “Brain Wise. Studies in Neurophilosophy” and Michael Gazzaniga’s (2005) “The Ethical Brain.” Basic assumptions about rational decision making in the consent process are based more on traditional philosophical (i.e, on-biological) assumptions of how people think and make decision than on evidence of how the brain consciously and unconsciously processes complex consent information to arrive at a decision. The prospective subject’s brain does not—or cannot—engage in rational decision making in ways that are consistent with Federal regulations and bioethical principles. Thus, it’s time to revise Federal regulations and ethical guidelines to take into account evidence-based research on how prospective subjects neurologically and intuitively arrive at their informed consent decisions.