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Informed Consent May Be Hazardous to Health

Before human subjects are enrolled in experimental studies, a variety of preliminary rituals are now required. These include an explanation of the nature of the experimental procedure and a specific elaboration of possible adverse reactions. The subjects, in turn, can either withdraw from the experiment or give their "informed consent." These rituals are said to increase the subjects' understanding of the procedures but, perhaps more important, they came into existence because of a strong belief in the fundamental principle that human beings have the right to determine what will be done to their minds and bodies.

Some, on the other hand, consider that the purpose of informed consent is not protection of subjects, but rather protection of investigators and sponsoring institutions from lawsuits based on the charge of subject deception should a misadventure result. But lawsuits arise in any case; subjects simply claim that they did not understand the rituals. It is reasonable, then, to ask whether the putative beneficiary, the subject, might be harmed rather than helped by the current informed consent procedure.

A considerable body of psychological evidence indicates that humans are highly suggestible. Information has been found to change people's attitudes, to change their moods and feelings, and even to make them believe they have experienced events that never in fact occurred. This alone would lead one to suspect that adverse reactions might result from information given during an informed consent discussion.

An examination of the medical evidence demonstrates that there is also a dark side to the placebo effect. Not only can positive therapeutic effects be achieved by suggestion, but negative side effects and complications can similarly result. For example, among subjects who participated in a drug study after the usual informed consent procedure, many of those given an injection of a placebo reported physiologically unlikely symptoms such as dizziness, nausea, vomiting, and even mental depression. One subject given the placebo reported that these effects were so strong that they caused an automobile accident. Many other studies provide similar data indicating that to a variable but often scarifying degree, explicit suggestion of possible adverse effects causes subjects to experience these effects. Recent hypotheses that heart attack may follow coronary spasm indicate physiological mechanisms by which explicit suggestions, and the stress that may be produced by them, might prove fatal. Thus, the possible consequences of suggested symptoms range from minor annoyance to, in extreme cases, death.

If protection of the subject is the reason for obtaining informed consent, the possibility of iatrogenic harm to the subject as a direct result of the consent ritual must be considered. This clear cost must be weighed against the potential benefit of giving some people an increased sense of freedom of choice about the use of their bodies. The current legalistic devices, which are designed in part to limit subject recourse, intensify rather than solve a dilemma.

The features of informed consent procedures that do protect subjects should be retained. Experimental procedures should be reviewed by peers and public representatives. A statement to the subject describing the procedure and the general level of risk is reasonable. But detailed information should be reserved for those who request it. Specific slight risks, particularly those resulting from common procedures, should not be routinely disclosed to all subjects. And when a specific risk is disclosed, it should be discussed in the context of placebo effects in general, why they occur, and how to guard against them. A growing literature indicates that just as knowledge of possible symptoms can cause those symptoms, so can knowledge of placebo effects be used to defend against those effects. A move in this direction may ensure that a subject will not be at greater risk from self-appointed guardians than from the experiment itself.—ELIZABETH F. LOFTUS *and* JAMES F. FRIES, *Center for Advanced Study in the Behavioral Sciences, Stanford, California 94305*