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INFORMED CONSENT

The National Institutes of Health now require a detailed description of the manner in which the "informed consent" of research patients is obtained. Researchers have been alarmed by the possibility that informing patients of the research nature of their treatment will limit the validity of results. Negative effects of informed consent in patients might include resentment about being used as research subjects or about being given supposedly inactive treatments (placebo), anxiety resulting from knowing that treatments are assigned arbitrarily, and poor response to treatments considered effective in a positively oriented nonresearch atmosphere. Furthermore, the researcher's guilt about "using" patients can be alleviated by the patient's ignorance of research goals.

In an attempt to evaluate the pros and cons of these issues, the authors have participated in the following studies: (1) a nonblind placebo trial in which patients were told that the capsules they were to be given were placebos; (2) a study in which patients were informed that two treatments were to be assigned arbitrarily in succession to test which treatment was more effective; (3) a survey of the patients' perceptions of the research procedures and goals in a drug study just completed, in which they had been subjected to multiple procedures including double-blind drug placebo, evaluation by several interviewers, role-playing by treating doctors, brief interviews, unexpected change of treating doctor after two interviews, completion of multiple forms, and one-way screen observation and recording of interviews.

By and large, patients came into the research with deep feelings of trust and expectations of marked improvement. Often they did not believe they were being subjected to research or given inert medication even when research paraphernalia were obvious and they were informed of the nature of the treatment. The doctor-patient relationship was apparently more important than the research procedures. In one study, special procedures with explanations appeared to facilitate the patient's response. When informed patients participated in the research, they were able to contribute information which would not have become available had they been kept ignorant of the research.

The welfare of the patient and doctor-patient rapport are better protected if patients are routinely informed about the research. The patient's preconceived notions and prior experiences determine his expectation to a degree that it is not easily shaken. Informed consent does not limit research, and indeed it may be a valuable asset to research design.

EFFECTS OF INFORMED CONSENT ON RESEARCH PATIENTS AND STUDY RESULTS

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Part II: The previous issue of Psychiatric Spectator contained other papers presented at this meeting.

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