

tients against unethical research. Our proposal recognizes and emphasizes the essential role of institutional review boards in this regard

In addition, there is a price that is paid when one insists on specific informed consent for all randomized, controlled trials. Many worthwhile studies will not be conducted if investigators are required to obtain specific informed consent. Many small but meaningful improvements in the quality of care will not occur if clinicians are forced to engage every patient in a dialogue about informed consent, especially when there is no reason to believe that the patient would have any preference regarding participation in the research. When unnecessary roadblocks prevent the easy evaluation of the comparative efficacy of new forms of technology and new interventions, these innovations tend to be adopted uncritically into practice. And this result is unfortunate, given that many of them would probably be found worthless or even harmful if subjected to formal evaluation in a clinical trial

These clinical and practical realities were recently acknowledged in the United States with regard to research under emergency conditions. For many years, research on emergency treatments was virtually paralyzed by the im-

possibility of obtaining informed consent from the subjects. For new therapies, such as the administration of hemoglobin substitutes in severe trauma and of thrombolytic agents in acute myocardial infarction, or new methods of performing cardiopulmonary resuscitation, systematic clinical trials could not be undertaken. In 1996, the FDA and the Department of Health and Human Services endorsed a waiver of informed consent for this type of research under certain clearly defined conditions. Although they acknowledged the importance of informed consent to medical practice, these agencies endorsed the waiver on the grounds that it would allow desperately ill patients access to new therapies and would result in important benefits to future patients. The agencies recognized that without the waiver, this important work would never be done.

We believe that the same rationale supports our proposal against the anticipated objections of those who prefer to see no exceptions made to the doctrine of informed consent. When benefits to society and to future patients can be gained without meaningfully compromising respect for patients' autonomy and without any serious increase in risk to those involved, blind insistence on informed consent is not only unnecessary, but also harmful.

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## 34 Human Experimentation and Human Rights

JAY KATZ

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### VI. THE NATURE OF THE INFORMED CONSENT PROCESS IN CLINICAL RESEARCH

If the tensions between the inviolability of research subjects and the advancement of knowledge are to be resolved in favor of respect for the human rights of the subjects, the mindset which investigators bring to the invitation of participation, the ethical principles which govern the invitation, and the conversations which physician-investigators and patient-subjects must engage in require re-examination. I shall take up each in turn.

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Jay Katz, "Human Experimentation and Human Rights," *St. Louis University Law Journal* 38 (1993): 7-54

#### A. *The Mindset of Physician-Investigators*

Physician-investigators, before approaching a potential patient-subject, must first rid themselves of the customary attitudes which in the past shaped, if not determined, their invitation to patient-subjects. A morally valid consent in research settings requires a radically new personal and professional commitment to the patient-subjects and the informed consent process: Physician-investigators must see themselves as scientists only and not as doctors. In conflating clinical trials and therapy, as well as patients and subjects, as if both were one and the same, physician-investigators unwittingly become double agents with conflicting loyalties. Only if they first know who they truly are can they begin to make the subject understand the burdens he or she is assuming when an invitation to participate in clinical trials is extended. Moreover, since loyalty to the research protocol will take precedence over faithful-

ness to the therapeutic mission, and since physician-investigators will tend to view the person before them as a patient and not as a subject, the tragic fact that human beings are used for the ends of others can readily become obliterated. It is then not surprising that physician-investigators, without fully knowing it, become confused about the nature of their task, as well as about their perceptions of themselves and their patient-subjects.

The investigators who appear before patient-subjects as physicians in white coats create confusion. Patients come to hospitals with the trusting expectation that their doctors will care for them. They will view an invitation to participate in research as a professional recommendation that is intended to serve their individual treatment interests. It is that belief, that trust, which physician-investigators must vigorously challenge so that patient-subjects appreciate that in research, unlike therapy, the research question comes first. This takes time and is difficult to convey. It can be conveyed to patient-subjects only if physician-investigators are willing to challenge the misperceptions that many patients bring to the invitation.

### B. *The Primacy of Autonomy*

Physician-investigators must extend the invitation to participation in research with a thoroughgoing commitment to the principle of autonomy. [...]

Respect for autonomy imposes numerous burdens on the physician-investigator. First, he must not allow disclosures to be shaped by paternalistic or beneficent concerns that patient-subjects will make decisions which are not in their "best interests." Second, he or she must not allow disclosures to be shaped by concerns that patient-subjects will learn that the customary treatments which they may continue to take, should they decline the more promising experimental treatments, offer no hope for the alleviation of their suffering. Nor should disclosures be shaped by concerns that patient-subjects' trust in medicine will be undermined once they learn about the uncertainties inherent in all medical treatments, nor by concerns over upsetting hospitalized patients if they were to appreciate that they, too, are being asked to yield their individual interests to the interests of scientific investigations.

Moreover, physician-investigators must reflect on the fateful impact of their commitment to the ideology of medical science—its ethos to acquire knowledge for the sake of mankind—on the invitation to participation in research. Medical scientists share with their colleagues from the natural sciences a commitment to the pursuit of truth, objectivity, and the advancement of knowledge. The commitment to objectivity invites investigators' thought processes to become objectified and, in turn, to transform the human beings who are the subjects of research into data

points to be plotted on a chart that will prove or disprove a research hypothesis.

Margaret Radin's observations about objectification illuminate this problem. In an article on women and people of color she noted that

[o]bjectification comes about through *subordination* when one culture conceives of certain characteristics of persons as marks of lesser personhood. These marks license manipulation of those who bear the marks, and also license refusal to recognize in them rights and other indices of respect otherwise conceived of as universally applicable to persons.

This license was usurped or conferred on physicians in clinical practice, and since the age of medical science has been extended to clinical research. Objectification begins with patients and becomes intensified when subordination is also affected by attitudes toward gender, color, religion, social and economic status, and, of course, by the scientific imperative of clinical research.

Furthermore, human beings should not be used lightly and cheaply to serve as means for the ends of others, even though they are so readily available in large numbers. Prior to extending an invitation to subjects, physician-investigators must give thought to the minimal number of subjects required for obtaining satisfactory answers to a research question and must conduct a literature search of existing studies which will make a repetition of an experiment unnecessary. Science's commitment to truth and progress, particularly when human beings are needed for purposes of research, ought to disdain inquiries where the truth is already apparent and progress already a reality.

Finally, as I have already suggested, physician-investigators must go to considerable length in extending the invitation to participate in clinical research so that they can rest assured that patient-subjects understand the implications of their consent. Pellegrino, in his discussion of "valid consent," sensitively describes the difficulty patients experience in "[separating] the physician-scientist role from the physician-healer." He further notes that "[t]he physician can easily obtain consent to an experimental protocol simply by emphasizing the hope of cure and downplaying the risk and the experimental nature of the treatment." He cautions physicians that "[a] legally adequate consent form may not be morally valid, [for a] morally valid consent aims at true 'con-sent,' an agreeing together."

Only respect for persons' autonomy and self-determination can guarantee "true 'con-sent,' an agreeing together"; otherwise, the invitation subtly becomes a request or even a demand. Invocation of the principle of beneficence, in the service of shielding patient-subjects from painful disclosures, can only mislead physician-investigators into

"downplaying the risk and the experimental nature of the treatment." Whenever beneficence suggests withholding of information, the better solution would be to exclude patient-subjects from participation in clinical research.

### C. *The Conversation*

To obtain a "morally valid consent [which] aims at true consent" is an inordinately difficult task. The physician-investigators must disclose to their subjects at least the following information: (1) that the subjects are not only patients and, to the extent to which they are patients, that their therapeutic interests, even if not incidental, will be subordinated to scientific interests; (2) that it is problematic and indeterminate whether their welfare will be better served by placing their medical fate in the hands of a physician rather than an investigator; (3) that in opting for the care of a physician they may be better or worse off and for such and such reasons; (4) that clinical research will allow doctors to penetrate the mysteries of medicine's uncertainties about which treatments are best, dangerous, or ineffective; (5) that clinical research may possibly be in the patient's immediate best interest, perhaps promise benefits in the future, or provide no benefit, particularly if the patient is assigned to a control (placebo) arm of a study; (6) that research is governed by a research protocol and a research question and, therefore, his or her interests and needs will yield to the claims of science; and (7) that physician-investigators will respect whatever decision the subject ultimately makes.

Conversing with patient-subjects in such a manner which will give them a clearer appreciation of the difference between clinical research and therapy is a daunting assignment. I have on occasions been asked, "How will investigators know when to stop the conversation?" My response has been that they will know when to stop once they have learned to begin the conversation with a commitment to respect for personhood; for only then will they not shirk their responsibility to be utterly forthright in disclosing the research dimension of their work and the alternatives available to their patient-subjects. It is the spirit in which the conversation begins which is the problem. If that problem is better resolved, the end will take care of itself.

Levine once wrote that in the current climate of extending the invitation to participation in research, "[the informed consent] requirement [serves] as a *pledge* made by researchers that in the pursuit of their salutary mission they will not exploit people; [or that i]ndividual persons will not be involved as research subjects without their awareness or approval" If he meant by "pledge" a symbolic gesture "to secure and maintain public confidence in scientific research," rather than a true commitment, I would agree.

Guido Calabresi years ago expressed his doubts about informed consent serving as a "control system" for the value

conflicts inherent in the conduct of research. He did not believe that it could in practice serve such a purpose. His argument was that "[c]onsent or its semblance keeps us from blatantly [destroying] the fabric of our commitment to human dignity." I am not convinced that informed consent need only serve such a limited symbolic function once the idea of shared decision making becomes a guiding commitment. Levine's and Calabresi's observations, however, identify the mutual deceptions in which scientists and the public engage in order not to unduly impede scientific research. The public, propelled by its longings to benefit from the advancement of science, has made common cause with scientists' demand for freedom of inquiry by acquiescing to the human costs which research entails. The symbolic bow to informed consent then allows the public and scientists to have it both ways. Forcing a public debate on the morality of human experimentation may put an end to the all too silent evasion of confronting any tragic choices that must be made. To be sure, "public confidence in scientific research" is justified on the ground that physician-investigators will take great care in not exposing patient-subjects to unnecessary *physical* harm. But this is a different matter.

The disclosure obligations I have set forth so far emphasize the need to pay particular attention to explaining to patient-subjects how participation in research differs from how they would ordinarily be treated or would expect to be treated. Thus, the first task in extending the invitation is to be absolutely clear about the research dimension of the invitation, its implications and possible consequences. Such disclosures do not require patient-subjects to understand the esoteric knowledge of medicine and science. Indeed, at present, subjects are overwhelmed with unnecessary scientific information that clarifies little and serves more the purpose of obscuring the crucial information that they need to know, such as the risks, benefits, alternatives, and uncertainties which patient-subjects face by their participation in clinical research, and the impact of participation, known and conjectured, on the quality of their future lives. Investigators have an obligation to translate scientific information into language which is relevant to patient-subjects' life and interests. Informed consent forms are so incomprehensible because they are written at a higher reading level than is appropriate for the intended population. In addition, they include too much distracting technical information of little consequence to the decisions which patient-subjects must make. Put another way, current informed consent forms often provide [institutional review boards] rather than the subjects with a better understanding of investigators' intentions.

Physician-scientists will be reluctant to converse with patient-subjects in the spirit of the recommendation that I have outlined. Such conversations take time, may have to extend over hours, perhaps even days, and must be continued until one is reasonably certain that the patient-subjects