than it destroys and solves more problems than it causes." However, it also found a trend in favor of slower economic growth. These slow-growth advocates are "most likely to be younger respondents—in the 18 to 25 age group, blacks and lower-income and less-educated respondents. It is somewhat ironical," the survey noted, "that these groups, who are most in need of jobs . . . are most skeptical about growth and technological progress." Overall, 60 percent said they thought science and technology do more good than harm, and only 5 percent said they do more harm than good.

Other polls commissioned since the nuclear accident at Three Mile Island—such as those done by CBS News and the *New York Times*, and by Harris for ABC News—registered a 16- to 23-point decline since 1975 in the support for nuclear plant construction programs. In addition, a poll released by Harris in May reported that Americans in the last 3 years have lost confidence in the ability of science to conquer disease. The clearest indication of the decline was a drop in the number of respondents—from 71 percent in 1976 to 55 percent in 1979—who thought a cure for cancer would be discovered by the end of the century. It may be wrong to interpret these findings as a decline in support for science and technology. They probably signal the growth of a more realistic public understanding of the limits of technology.

Amitai Etzioni, director of the Center for Policy Research at Columbia University, reads the declining figures as the manifestation of a general decline of faith in American institutions. He and a colleague, Thomas DiPrete, reviewed a group of Harris polls published over the last decade and concluded that they did not measure the weakness of particular institutions, but recorded a common and generalized feeling of alienation. "It follows," they wrote in a paper titled *The Decline in Confidence in America*, "that a problem largely common to all institutions cannot be remedied in any one alone; what is required of reformers is greater attention to the underlying societal structure." Incidentally, they found that the institution of science ranked second only to medicine, which ranked first every time in 10 years of polling.

Of the Three Mile Island accident, Etzioni said, "I don't think scientists are identified with it at all. It's executives, engineers, irresponsible operators. . . ." The public will have no difficulty making the distinction between nuclear physicists and utility company employees, he said, "unless a lot of nuclear scientists start running around defensively explaining that they're not at fault."

—ELIOT MARSHALL

Proposals for Ethics Boards Stir Debate

Recent shifts in policy have brought "widespread confusion" to Institutional Review Boards; and it may get worse

If you participate in this study, you will be exposed to certain risks of physical injury in addition to those connected with standard forms of therapy. These risks include (examples). In addition, it is possible that in the course of this study, new adverse effects that result in physical injury may be discovered. Medical therapy will be offered at no cost to you for any of the aforementioned physical injuries. You or your insurance carrier will be expected to pay the costs of medical care for physical injuries and other complications not mentioned in this paragraph since these are either associated with your disease or commensurate with the usual therapies for your disease. Federal regulations require that you be informed that—except as specified above—no financial compensation for injury is available.

The preceding was brought to you by the Human Investigation Committee of the Yale University School of Medicine, one of the nation's nearly 500 Institutional Review Boards (IRB's) that have been set up during the past decade to protect the rights of research subjects. The risk statement may not make you want to run out and volunteer for a research project at Yale, but don't bother looking somewhere else. As of 2 January 1979, all institutions that receive funds from the Department of Health, Education, and Welfare (HEW) must inform research subjects of the availability of financial compensation and medical treatment. Informing the patient is simple enough, but observers say that defining physical injury, for example, is almost impossible and that the regulation has caused "widespread confusion" at IRB's across the country. And it may get worse. In July, HEW will announce regulations that will *require* compensation to subjects for injuries suffered in HEW grant research. The federal government will not provide any coverage, however. Individual institutions and their IRB's are to foot the bill.

These changes are just the tip of the iceberg. New policy proposals are now circulating at several federal agencies, and the operation of IRB's may change drastically in other ways during the next few months. Changes called for include putting more lay members on the IRB's, testing the risk comprehension of research subjects, keeping records of IRB meetings for 5 years, and opening IRB meetings to the public.

Some say the changes will make IRB's more effective and will better protect the rights of research subjects. Others claim the proposals will tighten the grip of government to the point that research on humans will come grinding to a halt. Still others fear that increased visibility for IRB members will raise the risk of malpractice suits. Whatever the outcome for the IRB's themselves, the changes will be significant for the biomedical community, as some scientists complain that red tape and administrative delay have already slowed the research on human subjects.

The current confusion at IRB's and the spate of pending regulations have been greeted by a new journal that hopes to clarify some of the problems. *IRB: A Review of Human Subjects Research* will be published ten times a year by the Hastings Center. Its first issue came out this past March. The IRB proposals first surfaced last fall, when both the Food and Drug Administration (FDA) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued recommendations that are now becoming bureaucratic fact.

Not unexpectedly, debate over the

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proposed changes in federal IRB policy has been sharp, not only within the new journal, but all across the country, as was evident at a recent conference on clinical research that was held at the Center for Policy Study of the University of Chicago. One aspect of the conference quickly became a battle between lawyer and physician. Michael Sonnenreich, of Chayet and Sonnenreich in Washington, D.C., spouted doom and gloom, saying that mounting regulations for IRB's will "result in a dramatically diminished research effort in the United States." Sonnenreich, for instance, belittled the Commission's Belmont Report, which said that on occasion "it may be suitable to give some oral or written tests of comprehension" to a research subject. If such a recommendation were to become a regulation, said Sonnenreich, failure to test could end in a malpractice suit for an investigator or an IRB, even if an ethical and valid protocol were followed. "Since no one can, with any precision, determine when the 'occasion' for testing is needed," he said, "prudent counsel will instruct them to test each time to avoid suit." Thus, he noted, the "occasional" testing will become mandatory, and as it does the red tape will mushroom.

This raised the ire of some nonlawyers in the crowd. Robert Levine of the Yale medical school, who edits the new journal on IRB's and was a staff consultant to the Commission, called Sonnenreich's comments "simplistic generalizations of detailed regulations," and said it would be foolish to test all the time. Levine said, moreover, that the Commission wants to limit IRB red tape by eliminating written documentation of consent if the research presents small risks. In addition, he said, the Commission listed research areas where informed consent was not needed. An IRB, for example, would no longer be required to negotiate consent for studies on specimens removed at surgery when the piece of tissue would have otherwise been destined for the incinerator.

Sonnenreich noted, on the other hand, that the Commission also recommended that IRB records be kept for 5 years, and that IRB's determine not only that "selection of subjects is equitable," but that "the research methods are appropriate to the objectives of the research." In essence, said Sonnenreich, "each IRB is to become a petit FDA with written procedures, elaborate record keeping, and formalized hearings. These new roles proposed for the IRB will add significant costs to the research process. The administrative burdens placed on an IRB will ultimately alter the ability of small institutions to handle much research activity."

Levine was not shaken by this, and said that if anything, the authority of the IRB's should be strengthened. Take, for example, conflicts between the IRB's and the study sections at the National Institutes of Health (NIH). Levine said the study sections, which dish out many NIH grants, are making ethical decisions that ought to be made only by the IRB's, the upshot being stalled grants and slowed research. In a proposal prepared for one IRB, said Levine, investigators described the examinations they would use to identify high-risk subjects who would then be excluded from this study. The examinations satisfied the IRB, and the project was approved.

But the same project was not approved by the NIH study section. Members of this section concluded that although the experiment was designed to minimize risks, not all of them had been eliminated. "It appears," said Levine, "that this study section was operating with a zero risk standard for the justification of research on elderly subjects. Yet I am aware of no other individual or institution that has called for a zero risk in this or any other vulnerable population." The policy of the study sections, said Levine, should be changed. "I would direct them to proceed on the assumption that the IRB has ordinarily performed its function of ethical review. In the event they detect what seems to be a serious ethical impropriety, they should make telephone contact with the IRB to learn what information was available to the IRB to justify its approval." As it now stands, Levine noted, most investigators and IRB's accept study section decisions without a quarrel, not realizing that in the past some appeals have been sucessful. It is about time, he implied, to get tough.

Sonnenreich found Levine's suggestions beside the point and said that the consolidation of ethical authority would still not make up for the impending loss of scientific credibility. He said, for example, that the Commission's push for more lay members on the IRB's was for all intents and purposes a joke. "Judging scientific and medical issues of the greatest complexity should primarily be the job of trained scientists. Some representation by nonscientists may serve a watchdog function. However, in my opinion, one-third to two-thirds nonscientist representation on an IRB, as recommended by the Commission, alters its entire nature." (IRB's now generally have at least one lay member.) He also knocked the Commission's call to open the IRB meetings to the public. "It is difficult to imagine the kinds of review work which would occur at IRB meetings within the context of a town-meeting atmosphere."

The increased visibility for IRB members that will come with open meetings will raise the risk of legal liability, said Sonnenreich. There have already been suits against IRB members. The chairman of the University of Maryland's medical school IRB has been sued for approving research projects with jail inmates that did not provide adequate informed consent. And in California, an IRB member sued other IRB members to enjoin them from "approving, aiding, or abetting" a research project involving children. "It can be anticipated," said Sonnenreich, "that a variety of these types of litigation will occur at increasing rates with the newly proposed IRB changes."

This dreary prognostication struck at least one participant as an exaggeration. Levine said from the floor that the suit against the Maryland IRB was dismissed in January, and that the California action was merely an injunction, nothing more. The IRB's were not really in danger, he said, and implied that Sonnenreich was just using scare tactics.

"The IRB people will be sued," Sonnenreich shot back. "I guarantee you they will be sued. Fifteen years ago I could not have predicted the multimillion dollar malpractice settlements that are today being made. But in 10 to 15 years it is going to be the same with the IRB's." This apparently gave some participants at the conference cause for thought. Later in the meeting, after things had cooled off a bit, one physician said that he was not quite sure just whose side Sonnenreich was on.—WILLIAM J. BROAD

"It can be anticipated that a variety of these types of litigation will occur at increasing rates with the newly proposed IRB changes."