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Regulation of Human Experimentation

The scientific community should view with caution the current drive to set up government regulation of the use of human subjects in research (*Science*, 19 October, p. 265). Too often, in too many countries, authorities, in the name of some worthy cause or another, have imposed restrictions on the freedom of inquiry.

Serious abuses of free inquiry have undeniably occurred. As one example, researchers studying syphilis among poor blacks in Tuskegee, Alabama, allowed the disease to run its course so they could complete their investigation of its long-term effects. Such abuses involve only a tiny minority of investigators. Nevertheless, the transgressors are researchers, and a lay person can hardly distinguish between them and the overwhelming majority of ethical scientists.

The abuses have not gone unnoted. Hearings, held first by Senator Walter Mondale, and more recently by Senator Edward Kennedy, have focused the attention of Congress, the Department of Health, Education, and Welfare, the media, and the public on these problems. The World Health Organization and HEW have formulated a variety of regulations, including creation of ethical review boards that could withhold prior approval of research involving human experimentation and could sanction violators. A tough regulatory bill drafted by Kennedy's staff and approved by the Senate, but not yet by the House, hangs over us (*Science*, 19 October, p. 265).

The scientific community should not delay setting up its own ethical standards and regulatory mechanisms for dealing with possible abuse of human subjects. The reasons are compelling. First, subjects do need protection, and if scientists can agree together to provide it, it can be done in ways that will not unduly bureaucratize or hobble science. Second, government regulations are aimed chiefly at "federally funded programs"; persons serving as subjects in other research—especially that funded by drug manufacturers—need protection at least as badly. Third, concern with the humanitarian aspect of scientific work should not have to be imposed on researchers. Researchers should express their commitment to solving this problem by voluntarily providing effective mechanisms for dealing with it.

The first rung of such a voluntary review ladder should be local human-subject review committees composed of scientists; persons from other academic disciplines, such as humanities, law, theology; and some representatives of the subjects themselves. The next rung should be constituted of regional appeal boards. The highest should be a nationwide board, with the same composition as the local ones but involving persons of national stature, to evolve review standards and clarify generic questions.

A project passed upon would be issued a certificate of approval. One would expect that the various government agencies, as well as foundations, would be quick to agree not to support unapproved studies. Prisons, schools, mental hospitals, and other institutions that have captive or underage populations would not allow unapproved researchers access to their populations. Authorities of such institutions would thus back up standards formulated by the scientific community, rather than set standards themselves. The few investigators who would continue to conduct unapproved research would soon find themselves cut off from the scientific community and from sources of reputation and legitimation and their work branded as unethical. If the scientific community does not act, government regulations will and should follow.—AMITAI ETZIONI, Professor of Sociology, Columbia University, and Director, Center for Policy Research, Inc., 475 Riverside Drive, New York 10027

For additional material, see B. Barber, J. Lally, J. L. Makarushka, D. Sullivan, *Research on Human Subjects* (Russell Sage Foundation, New York, 1973); J. Katz, Ed., *Experimentation with Human Beings* (Russell Sage Foundation, New York, 1972); A. Etzioni, *Genetic Fix* (Macmillan, New York, 1973).