

Title 45-Public Welfare

SUBTITLE A-DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 46-PROTECTION OF HUMAN SUBJECTS

Secretary's Interpretation of "Subject at Risk"

Notice is hereby given of the Secretary's interpretation of his regulations at 45 CFR 46.103 (b), defining "subject at risk." The definition is incorporated in 45 CFR Part 46, pertaining to the Protection of Human Subjects involved in grants and contracts of the Department of Health, Education, and Welfare supporting research, development and related activities.

Section 46.1.03(b) defines "subject at risk" at "any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 U.S.C. 2891-3 (added by Pub. L. No. 93-343), which forms part of the basis for the Departmental regulations at 45 CFR Part 46, and in the preambles to the proposed and final regulations at 45 CFR Part 46. The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psychosurgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devices; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study: the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human *in vitro* fertilization. The regulations were intended, and have been uniformly applied by the Department, to protect human subjects against the types of risks inherent in these types of activities,

The regulations were not, and have never been, intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual. More particularly, they were not designed to protect against possible financial injury, which may result from alteration in the price, availability, or conditions of eligibility for benefits or services offered under a governmental program. Thus, a requirement for research and development purposes that some welfare recipients report more frequently than others their income for purposes of determining their eligibility for, or the amount of, their welfare benefit, or a requirement that some but not all able-bodied recipients work as a condition of eligibility for welfare, or a diminution in the level of welfare benefits (within prescribed boundaries) payable to some but not all similarly situated welfare beneficiaries, or a requirement that some but not all welfare recipients make a co-payment toward the cost of governmentally-financed medical care would not constitute burdens or effects of the nature that the regulations are intended to encompass and, therefore, would not place the individuals subject to those burdens or effects "at risk" within the meaning of the regulation. In the context of the regulations, there would be no departure from the range of "established and accepted methods necessary to meet [the] needs [of the individual]" in these types of circumstances.

The standard for measuring any departure from "established and accepted methods" with respect to activities designed to test the effect of social and economic change has traditionally been intended by the Department to include the range of experience of the average American in his daily life. Thus, with respect to work requirements for able-bodied welfare recipients, the standard for determining such a departure would be the experience of the average able-bodied American who must work to obtain his sustenance rather than the experience of most welfare recipients who do not work. Similarly, subjecting a group of people to a requirement that they report income for purposes of obtaining governmental benefits, or causing a lowering of their income, or requiring them to make some payment toward the cost of their medical care would not depart from the normal experience which other Americans can expect to encounter in their daily lives, and would thus not constitute the type of departure from "ordinary and accepted methods" to which the regulations were intended to apply.

Moreover, the regulations are not intended to protect individuals from the "ordinary risks of daily life." There are certain risks which may reasonably be expected to be encountered by anyone, for example, the risks inherent in having to make a decision as to how to allocate funds, or in deciding whether to meet certain conditions, such as performing work, which are required in order to obtain funds. The exposure to the risks which emanate from these choices does not constitute the type of situation against which the Department's regulations are designed to guard.

This interpretation of the regulation is consistent with the preambles to the proposed and final regulations that now appear in Part 46 and with Departmental practice in implementing those regulations.

Dated: June 24, 1976

DAVID MATHEWS,
Secretary.

[Federal Register Doc.76-18850 Filed 6-25-76; 8:45 am]