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Part II

Department of Health and Human Services

Office of the Secretary

Exemption of Certain Research and
Demonstration Projects From Regulations
for Protection of Human Research
Subjects

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 46

Exemption of Certain Research and Demonstration Projects From Regulations for Protection of Human Research Subjects

AGENCY: Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (the Department or HHS) is proposing to include among the types of research specifically exempt from the application of the regulatory requirements of 45 CFR Part 46 (protection of human research subjects), research and demonstration projects conducted under the Social Security Act and other Federal statutory authority and designed to study certain public benefit or service programs, the procedures for obtaining benefits or services under those programs, and possible changes or alternatives to those programs or procedures, including changes in methods or levels of payment. This proposed amendment to the revised final regulations for protection of human research subjects (published January 26, 1981) would in effect, restore to the regulations on exemption included in the initial notice of proposed rulemaking (NPRM) (published August 14, 1979). These demonstration and service projects are already subject to procedures which provide for extensive review by high level officials in various program administration offices. Review by an IRB would be duplicative and burdensome to state and local agencies and to other entities participating in demonstration projects. Removal of an unnecessary layer of review will not only reduce the cost of the projects but help to avoid unnecessary delays in project implementation.

DATE: Written comments are due by April 21, 1982.

ADDRESS: Please send comments or requests for additional information to: F. William Dommel, Jr., J. D., Assistant Director, Office for Protection from Research Risks, Public Health Service, 5333 Westbard Avenue, Room 3A-18 Bethesda, Maryland 20205. Telephone: (301) 496-7163.

FOR FURTHER INFORMATION CONTACT: F. William Dommel, Jr.: (301) 496-7163.

SUPPLEMENTARY INFORMATION: In an NPRM Published August 14, 1979 (44FR

47688), the Department proposed amendments to the basic HHS Policy for the Protection of Human Research Subjects, 45 CFR Part 46, and included an exemption from these regulations for research "designed to study on a large scale: (A) The effects of proposed social or economic change, or (B) methods or systems for the delivery of or payment for social or health services." Public comment on this section of the NPRM focused on the lack of clarity of its wording, and in particular the vagueness of the phrase "on a large scale." (See discussion in the preamble to the final amended regulations, 46 FR 8366, 8370, January 26, 1981.) No significant questions were raised and few adverse comments were made about exempting from institutional review board (IRB) scrutiny, research which involves the study of existing public benefit or service programs and possible changes in or alternatives to those programs. However, at the time of publication of the final regulations, the Department did not elect to include this exemption, but instead, as a policy matter, found IRB review "appropriate" for such research, while permitting waiver of informed consent, when it is found to be "impracticable" (46 FR 8383).

The principal authority for the regulations in part 46 is found in section 474 of the Public Health Service (PHS) Act under which the Secretary is required to establish by regulation review procedures for "the conduct of biomedical and behavioral research involving human subjects." This legislation does not specifically address research and demonstration projects designed to study public benefit or service programs which are conducted under the Social Security Act and other statutory authority. The Department again proposes to exempt certain projects of this kind as it previously proposed to do in the NPRM published August 14, 1979 (44 FR 47688). The specific wording of the exemption, however, has been modified in response to public comments which the Department received concerning the language proposed earlier. These comments call for greater clarity and specificity in the wording of the exemption.

There are several reasons why the Department considers such an exemption to be appropriate. First, these demonstration and service projects are already subject to procedures which provide for extensive review by high level officials in various program administration offices. Review by the IRB would be duplicative and burdensome to state and local agencies and to other entities participating in

demonstration projects. Removal of an unnecessary layer of review will not only reduce the cost of the projects but help to avoid unnecessary delays in project implementation.

Second, it is reasonable to assume that when the Congress directed that public benefit and service programs be carried out, it also expected the funding agencies to be able to evaluate them without subjecting the evaluation efforts to review and possible disapproval by IRB's.

Finally, the Department believes that the review procedures set forth in the current regulations are not well suited for demonstration projects involving public benefit and service programs. The Department has already provided for waiver of some or all of the consent procedures which are appropriately required for other kinds of research, but which may not be practicable for demonstration projects. The exemption proposed herein is simply a logical extension.

Under the proposed exemption, research and demonstration projects with the following statutory authorities would be among those exempted from the Part 46 requirements: Sections 426, 445, 1110(a), 1115 and 1875 of the Social Security Act; sections 201 (a) and (b) and section 505 of the Social Security Disability Amendments of 1980, Pub. L. 96-265; Section 402(a) of the Social Security Amendments of 1967, as amended (codified at 42 U.S.C. 1395b-1); section 222(a) of the Social Security Amendments of 1972 (codified at 42 U.S.C. 1395b-1 note); section 649 of Pub. L. 97-35 (Head Start Act); section 4 of Pub. L. 93-247, as amended (Child Abuse Prevention and Treatment Act); section 145 of Pub. L. 91-517, as amended (Developmental Disabilities Assistance and Bill of Rights Act); section 805 of Pub. L. 93-644, as amended (Native American Program Act of 1974); sections 421-425 of Pub. L. 93-29, as amended (Older Americans Act of 1965).

Impact Analysis

Economic Impact on Small Entities

The Secretary certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, Pub. L. 96-354. Thus, a regulatory flexibility analysis is not required.

Classification of Rule Under E.O. 12291

The Secretary has determined that this rule is not a "major rule" under Executive Order 12291 and thus a

regulatory impact analysis is not required. The Secretary's determination is based on the finding that the proposed rule would not:

- (1) Have an annual effect on the economy of \$100 million or more;
- (2) Impose a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or
- (3) Result in significant adverse effects on competition, employment investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Notice is given that it is proposed to make any amendment that is adopted, effective upon publication in the Federal Register.

Dated February 1, 1982.
Edward N. Brandt, Jr.,
Assistant Secretary for Health.
 Approved: February 25, 1982.
Richard S. Schweiker,
Secretary.

PART 46—PROTECTION OF HUMAN SUBJECTS

For the reasons set out in the preamble, Part 46 of 45 CFR is proposed to be amended by adding a new paragraph (6) to § 46.101(b) to read as follows:

§46.101 [Amended]
* * * * *

(b) * * *

(6) Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the

Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) Programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

* * * * *

§46.116 [Amended]

Additionally § 46.116(c) is to be removed and § 46.116 (d), (e) and (f) are to be redesignated as § 46.116 (c), (d) and (e) respectively.

(FR Doc. 82-7565 Filed 3-19-82; 8:45 am)

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