

Registered
Order

FRIDAY, NOVEMBER 3, 1978

PART IV



**DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE**

Office of the Secretary



**PROTECTION OF HUMAN
SUBJECTS**

**Informed Consent; Definition
Amended To Include Advice on
Compensation**

[4110-08-M]

Title 45—Public Welfare

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

PART 46—PROTECTION OF HUMAN SUBJECTS

Informed Consent — Definition Amended To Include Advice on Compensation

AGENCY: Department of Health, Education, and Welfare.

ACTION: Interim final regulation.

SUMMARY: The Department of Health, Education, and Welfare hereby amends the definition of informed consent in its regulations on protection of human subjects, by requiring that prospective subjects be advised as to the availability or nonavailability of medical treatment or compensation for physical injuries incurred as the result of participating in biomedical or behavioral research.

EFFECTIVE DATE: January 2, 1979.

ADDRESS: Comments and requests for information and requests for additional copies of this notice to: Robert Backus, Ph. D., Acting Director, Office for protection From Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, 301-496-4705.

SUPPLEMENTARY INFORMATION: On May 30, 1974, the Department of Health, Education, and Welfare published in the FEDERAL REGISTER regulations for the protection of human subjects (39 FR 18914). These regulations (codified at 45 CFR Part 46) include a requirement that no subject may be involved in activities covered by the regulations, which would place the subject at risk, unless legally effective informed consent is first obtained from the subject or the subject's legally authorized representative. Section 46.103(c) of the regulations sets forth a detailed definition of "informed consent" including six basic elements of information necessary to such consent.

Shortly thereafter, a Department task force was formed to develop a mechanism to compensate persons injured as a result of their participation in research. The task force issued a report in January 1977 making a number of recommendations for com-

pensating injured subjects (DHEW Publication No. OS-77-003). This report was sent to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for comment. The Commission's reply, received in June 1977, was generally favorable to the task force's recommendations. However, the Commission urged that the existence or absence of a compensation mechanism be disclosed as part of the informed consent process.

More recently, in its own Report and Recommendations on Institutional Review Boards (IRBs) dated September 1, 1978, the Commission recommended that subjects should be informed "whether treatment or compensation is available if harm occurs" (HEW Publication No. OS-78-008, at page 21). The Department will be publishing the Commission's recommendations on IRBs in the FEDERAL REGISTER for Public Comment.

The Department believes, however, that, at least where research presents risk of physical harm. Subjects should be advised at the outset whether there will be any financial protection for them in the event they are injured. The public interest would therefore be served by adding this element of information to the Department's informed consent requirements as soon as possible. I therefore find that good cause exists for issuing this as an interim final regulation, subject to possible future changes after consideration of public comment.

Consequently, pending consideration of, and response to the Commission's overall recommendations on IRBs, the Department is hereby amending the definition of informed consent along lines suggested by the Commission. Since the amendment is being adopted prior to public comment, its scope will be limited to treatment and compensation for physical injury, and only to those physical injuries arising from biomedical or behavioral research. Also, it will be extended to research conducted in collaboration with foreign governments or international organizations, absent the explicit nonconcurrency of those governments or organizations.

The amendment to the regulations will be effective on a prospective basis, on January 2, 1979. After that date, IRBs, in carrying out their normal responsibilities for review of new research proposals and ongoing projects, under 45 CFR Part 46, shall utilize the definition of informed consent in section 46.103(c), as amended.

Although the amendment is being adopted as an interim final regulation, public comment is requested both on the basic issue of advising subjects regarding the availability or nonavailability of compensation and medical treatment for injuries and the specific amendment itself, including the limitations on its scope. The Department recognizes that limiting the amendment to the regulations to Physical injury and to biomedical and behavioral research may be artificial and unduly restraining. At the same time, however, the Department is reviewing the issue of the applicability of the affected regulations and the scope and substance of this amendment will be examined in light of the outcome of that review.

Dated: September 5, 1978.

CHARLES MILLER,
Acting Assistant Secretary for Health.

Approved: October 21, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

Accordingly, Part 46 of 45 CFR, Subtitle A, is amended by:

1. Deleting the word "and" at the end of § 46.103(c)(5).
2. Changing the period at the end of § 46.103(c)(6) to a semicolon, and adding the word "and" after the semicolon.
3. Adding the following new § 46.103(c)(7):

§ 46.103 Definitions.

* * * * *

(c) ***

(7) With respect to biomedical or behavioral research which may result in physical injury, an explanation as to whether compensation and medical treatment is available if physical injury occurs and, if so, what it consists of or where further information may be obtained. This subparagraph will apply to research conducted abroad in collaboration with foreign governments or international organizations absent the explicit nonconcurrency of those governments or organizations.

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