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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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PROTECTION OF HUMAN SUBJECTS

Proposed Amendments Concerning Fetuses, Pregnant Women, and In Vitro Fertilization

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

[45 CFR Part 46]

PROTECTION OF HUMAN SUBJECTS

Proposed Amendments Concerning Fetuses, Pregnant Women, and In Vitro Fertilization

On August 8, 1975, final regulations were published in the FEDERAL REGISTER (40 FR 33526) relating to research supported by the Department involving fetuses, pregnant women, and in vitro fertilization. These regulations are codified in 45 CFR, Part 46, Subpart B. Also published in the same issue of the FEDERAL REGISTER were the Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (40 FR 33530).

As required by Pub. L. 93–348, section 205, the Secretary announced that he would take into consideration any comments submitted regarding the Recommendations and would proceed to any further rulemaking with respect to any amendments to the regulations which might appear warranted.

Comments on the Recommendations of the National Commission were accepted through the middle of January 1976. The great majority of these comments addressed issues discussed both in the preamble to the final regulations published on August 8, 1975, and in the preamble to the notice of proposed rulemaking published in the FEDERAL REGISTER on August 23, 1974 (39 FR 30648), which preceded the final regulations. Consequently, there seems no reason to repeat these discussions here.

Some comments were addressed to substantive issues not considered in the earlier proposed rulemaking. Specifically, several comments were received suggesting that the term "fetus" be redefined to mean the product of conception from the time of conception, rather than from the time of implantation, since the phrase "confirmation of pregnancy" did not define a specific, recognizable point in time. Designation of the time of implantation as the beginning of the fetal period is a matter of practical medical and regulatory necessity. No medical tests exist which can confirm conception. Numerous tests exist which can confirm implantation on the basis of the hormonal changes which occur as a result of that process. However, the Department agrees that the regulations implementing the Recommendations should not appear to ignore the generally accepted signs of the presence of the fetus, such as missed menses, or the need in some instances to establish the presence or absence of the fetus by more sensitive medical tests. Therefore, the Department proposed to amend §§ 46.102(c), 46.203 (b), and 46.203(c) of the implementing regulations to indicate that these signs and tests shall be employed, as appropriate, to establish the presence or absence of the fetus.

Another group of comments was directed to those definitions concerned with the concept of viability as it applies to the fetus *ex utero.* The criticisms of "viability" centered upon concern that the term could be interpreted loosely to permit any type of nontherapeutic research. Use of the term "fetus *ex utero"* was also criticized as a device to include "infants" together with fetuses. Having considered these criticisms, the Department notes that both it and the Commission were quite aware of the medical uncertainty surrounding the term "viability" both with respect to the individual fetus *ex utero* or infant, and with respect to fetuses historically as reflected by the steady improvement in fetal survival rates over the past several decades. The definitions of fetal viability and death are discussed at some length in the Commission's Report (40 FR 33542). The Commission notes at one point that "* * * no cases were found from any documentable source of any infant surviving with a birth weight below 600 grams at a gestational age of 24 weeks or less." To insure against medical error in determining viability, the Commission recommended, and the Department concurred, that a still lower limit of 500 grams and 20 weeks or less be established as guidelines to assist in distinguished the "Nonviable fetus * * * *ex utero"* from the viable infant. In order to permit further lowering of this limit in advance of improvements in fetal survival, the Department's implementing regulations provided that "The Secretary may from time to time * * * publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable * * *." A notice setting forth these guidelines was published in the same FEDERAL REGISTER as the regulations (40 FR 33552). The term "fetus *ex utero"* was used to maintain consistency with the terms of Pub. L. 93–348. Section 202(3)(b) of that law required the Commission to conduct an investigation and study of the nature and extent of research involving living fetuses generally. Section 213 referred to the fetus "before or after the induced abortion of such fetus," even though the product of an abortion is by custom termed an "abortus." The terms "fetus *in utero"* and "fetus *ex utero"* are therefore necessary distinctions, even though most of the regulations can be written applying uniformly to the fetus, as in the "minimal risk" provisions of § 46.206. No changes are proposed with respect to the use of the terms "viability" or "fetus *ex utero."*

The Commission implicitly recommended the establishment of "a national ethical review body." The provisions of § 46.204 would establish two Ethical Advisory Boards, one to serve the Public Health Service and the other to serve all other agencies and components of the Department. The Department received only a few comments about the issue of review bodies. Those comments, however, served to emphasize the inflexibility of § 46.204 which would create a review system along organizational rather than program lines and which would not permit the establishment of additional Boards which might be required. The Department therefore proposes to amend § 46.204(a) by changing the first sentence to read: "One or more Ethical Advisory Boards shall be established by the Secretary," deleting § 46.204(b) and making such other editorial and numbering changes as are required.

The largest group of the criticisms received were concerned with the Commission's recommendation on nontherapeutic research after abortion, and the Department's interpretation of these in § 46.209. Specifically, it was noted that the Commission's recommendation 6(h) that "* * * no intrusion into the fetus (be) made which alters the duration of life" was not codified in the regulations. Instead, the Department's implementing regulation stated at § 46.209(b) (1) that "vital functions of the fetus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability."

In a letter dated October 29, 1975, to the Secretary, the Commission took issue with this provision noting that:

> In its accumulation of facts on the subject and in the taking of public testimony of scientists, the Commission was not made aware of any compelling evidence that nontherapeutic testing of vital function support mechanisms, such as keeping a nonviable fetus on a perfusion pump, artificial lung or artificial placenta, was needed for the desired advances in medical technology. Success in the newborn nursery in keeping small babies alive has, however, been accomplished in a strictly therapeutic setting. The nonviable fetus considered for such research under the regulations as presently worded would be under 20 gestational weeks of age. The frontier for such research is on the "possibly viable" infant in the 20 to 24 week category according to our definitions. Research on the small nonviable fetus which involved artificial maintenance of life by perfusion techniques and then withdrawal of such support was objected to by all segments of the public, including scientists who in public testimony did not defend the practice when specifically questioned about it. The Commission recommends that § 46.209(b) (1) be amended, so that study of life support mechanisms to bring viability to smaller infants is restricted to the borderline period of 20–24 weeks, until such time as a lower age/weight definition of viability is determined by the Ethical Advisory Board, and that such study be conducted with the intent and expectation of saving the infant's life. To do otherwise might permit the sort of research that has been found most objectionable by the public and led to the formation of this Commission by Congress.

On review of § 46.209(b) (1) it became evident that the provision did not adequately reflect the Department's actual intent, simply to permit artificial maintenance of vital functions only to enable the particular fetus "to survive to the point of viability." The Department proposes to amend § 46.209 accordingly.

Written comments, criticisms and inquiries concerning these proposed amendments are invited from interested persons, institutions and organizations. Letters should be addressed to the Di-

rector, Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. Additional copies of these proposed amendments and/or of the current regulations may be obtained by writing to the same address.

All comments received become available to the public for inspection and copying at the National Institutes of Health, Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9 am. and 4:30 p.m. All comments received on or before (60 days after publication) will be considered.

Notice is hereby given that it is proposed to make any amendments that are adopted effective upon their publication in the FEDERAL REGISTER.

The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A–107.

Dated: November 10, 1976.

THEODORE COOPER,
Assistant Secretary for Health.

Approved: January 5, 1977.

MARJORIE LYNCH,
Acting Secretary.

It is therefore proposed to amend Part 46 of 45 CFR, Subtitle A, by:

1. Revising § 46.102(c) to read:

§ 46.102 Policy.

* * * * *

(c) Unless the activity is covered by Subpart B of this part, if it involves as subjects women who could become pregnant, the Board shall also determine as part of its review that adequate and appropriate steps will be taken to avoid involvement of women who are in fact pregnant (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), when such activity would involve risk to a fetus.

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2. Revising §§ 46.203(b) and 46.203(c) to read:

§ 46.203 Definitions.

* * * * *

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses or a medically acceptable pregnancy test) until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test) until a determination is made, following explusion or extraction of the fetus, that is viable.

* * * * *

§ 46.204 [Amended]

3. Revising § 46.204(a) to read:

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Board(s) shall be so selected that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Federal Government.

* * * * *

4. Deleting § 46.204(b) and redesignating §§ 46.204(c) through 46.204(e) as §§ 46.204(b) through 46.204(d).

5. Amending § 46.204(b), as so redesignated, by deleting the word "appropriate" wherever it occurs.

6. Amending §§ 46.209(a) and 46.209 (b) to read:

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:

(1) (i) There will be no added risk to the fetus resulting from the activity, and

(ii) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subpart in an activity covered by this subpart unless;

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

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