

Report and  
Recommendations

# Research on the Fetus

The National Commission  
for the Protection of  
Human Subjects  
of Biomedical and  
Behavioral Research

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1975

**NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS  
OF BIOMEDICAL AND BEHAVIORAL RESEARCH**

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## I.

### THE MANDATE

The National Research Act (P.L. 93-348) established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and gave the Commission a mandate to investigate and study research involving the living fetus, and to recommend whether and under what circumstances such research should be conducted or supported by the Department of Health, Education, and Welfare. A deadline of four months after the members of the Commission took office was imposed for the Commission to conduct its study and make recommendations to the Secretary, DHEW. The priority assigned by Congress to research involving the fetus indicates the concern that unconscionable acts involving the fetus may have been performed in the name of scientific inquiry, with only proxy consent on behalf of the fetus.

The members of the Commission determined at the outset to undertake a careful study of the nature and extent of research on the fetus, the range of views on the ethical acceptability of such research, and the legal issues involved, prior to formulating their recommendations. To this end, the Commission has accumulated an extensive body of information, held public hearings, questioned a panel of distinguished ethicists, and conducted lengthy deliberations. In the course of these activities, the Commission has given close scrutiny to many important questions that surround research on the fetus, for example: What are the purposes of research on the fetus? What procedures have been employed in such research? Are there alternatives to such research? Can appropriate consent to such research be obtained by proxy? Under what conditions may research be done on a fetus that is to be aborted, or a nonviable delivered fetus? What review of proposed research should be required?

In the remainder of Section I, the background and activities of the Commission are summarized, and the definitions used in this report are set forth. Reports, papers and testimony that were prepared for or presented to the Commission are summarized in Sections II to VII of this report. The Commission's own

statement of its deliberations and conclusions appears in Section VIII, and the recommendations themselves are set forth in Section IX, together with a statement by a member of the Commission dissenting in part from the recommendations. Separate views of members of the Commission are set forth in Section X.

The Appendix to the report contains the entire text of the papers and reports that were prepared under contract to the Commission, and certain other materials that were reviewed by the Commission during its deliberations.

Legislative Background. The National Research Act contains two provisions regarding research on the fetus: (1) the mandate to the Commission to conduct studies and make recommendations to the Secretary, DHEW, (section 202(b)), and (2) a prohibition, in effect until the Commission has made recommendations, on "research [conducted or supported by DHEW] in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus" (section 213). These two provisions were drafted by a conference committee that resolved the differences between the acts originally passed in 1973 by the House of Representatives and Senate, respectively.

The original House act contained a prohibition against the conduct or support by DHEW of research that would violate any ethical standard adopted by the National Institutes of Health or the National Institute of Mental Health. This provision was perceived as a prohibition of research on the living fetus, as a result of policy then in force at NIH. In addition, both the House and Senate acts contained floor amendments explicitly prohibiting the conduct or support of research on the fetus by DHEW. The House amendment, adopted by a vote of 354 to 9, proscribed research on a fetus that is outside the uterus and has a beating heart, while the Senate prohibition applied to research in connection with an abortion. Among other differences between the acts, the House prohibitions were permanent, while the Senate prohibition was temporary. The conference committee adopted the Senate approach, imposing a moratorium until this Commission made recommendations. The moratorium adopted by the conference committee applies to research conducted on a fetus before or after an induced abortion of the fetus (except to assure the survival of the fetus); the mandate for the Commission's study and recommendations applies more generally to research involving the living fetus.

The Commission has reviewed the committee reports (Nos. 93-244, 93-381, and 93-1148) and the record of the floor debate that led to the passage of the National Research Act (Congressional Record, daily eds. May 31, 1973; September 11, 1973; June 27 and 28, 1974). Other legislative materials that have been reviewed include the Hearings on Biomedical Research Ethics and the Protection of Human Subjects, before the House Subcommittee on Public Health and Environment (September 27 and 28, 1973), and the Hearing on Fetal Research before the Senate Subcommittee on Health (July 19, 1974).

It is clear from the legislative history that the National Research Act, as passed by both Houses and signed into law by President Nixon on July 12, 1974, reflects an acknowledgement by the majority of legislators that the issues surrounding research on the fetus require much study and deliberation before policies are established regarding support by the Secretary, DHEW. That assignment was given to the Commission, and this report describes how the assignment was carried out and the conclusions that were reached.

Existing Codes and Other Relevant Material. To assist its deliberations, the Commission referred to the following pre-existing codes and other materials relating to human experimentation:

1. The Nuremberg Code (1946-1949).
2. The Declaration of Helsinki (revised, 1964).
3. The Use of Fetuses and Fetal Material for Research, Report of the Advisory Group, chaired by Sir John Peel (London, 1972).
4. Protection of Human Subjects: Policies and Procedures, draft document of the Department of Health, Education, and Welfare (38 Federal Register No. 221, Part II, November 16, 1973).
5. Protection of Human Subjects: Proposed Policy, Department of Health, Education, and Welfare (39 Federal Register No. 165, Part III, August 23, 1974).

(The above documents are included in the Appendix to this report.)

Meetings of the Commission. Secretary Weinberger administered the oath of office to the members of the Commission on December 3, 1974, thereby fixing the deadline for this report. Section 202(b) of the National Research Act requires that recommendations of the Commission with respect to research on the living fetus be transmitted to the Secretary "not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all members of the Commission have taken office." This 4-month period expired April 30, 1975.

The Commission conducted seven meetings devoted primarily to the topic of research on the fetus. These meetings were well attended by the public. One day of the February meeting was devoted to a public hearing of the views of persons interested in research on the fetus; oral testimony was given by 23 witnesses, some representing research, religious or other organizations and some appearing as concerned citizens to express their viewpoints (see Section VI for summaries of the views presented). At the March meeting, three public officials testified about the involvement of their respective agencies or offices in research on the fetus (see Section VI), and the members of the Commission held a roundtable discussion with several ethicists who had prepared papers covering a wide spectrum of secular opinion and religious persuasion (see Section V for summaries of these papers).

Studies and Investigations. The Commission contracted for a number of studies and investigations. These included a study, undertaken primarily through review of the literature, of the nature, extent and purposes of research on the fetus, conducted under contract with Yale University (see Section II); an historical study of the role of research involving living fetuses in certain advances in medical science and practice, conducted under contract with Battelle-Columbus Laboratories (see Section III); and a study utilizing available data to establish guidelines for determining fetal viability and death, conducted under contract with Columbia University (see Section VII).

In addition to these studies, papers outlining their views on research on the fetus were prepared by the following ethicists and philosophers: Sissela Bok of Harvard University; Joseph Fletcher of the Institute of Religion and Human Development; Marc Lappé of the Hastings Institute of Society, Ethics, and the

Life Sciences; Richard McCormick and LeRoy Walters of the Kennedy Institute for the Study of Human Reproduction and Bioethics; Paul Ramsey of Princeton University; Seymour Siegel of the Jewish Theological Seminary; and Richard Wasserstrom of the University of California at Los Angeles (see Section V). Stephen Toulmin, of the University of Chicago, prepared an analysis of the ethical views that were presented to the Commission, identifying areas of consensus as well as divergence. Leon Kass, of Georgetown University, prepared a philosophical paper on the determination of fetal viability and death (see Section VII). Papers on the legal issues of research on the fetus were prepared by Alexander M. Capron of the University of Pennsylvania Law School, and John P. Wilson of Boston University Law School (see Section IV).

(All of the above studies, investigations and papers appear in the Appendix.)

Definitions. For the purposes of this report, the Commission has used the following definitions which, in some instances, differ from medical, legal or common usage. These definitions have been adopted in the interest of clarity and to conform to the language used in the legislative mandate.

"Fetus" refers to the human from the time of implantation until a determination is made following delivery that it is viable or possibly viable. If it is viable or possibly viable, it is thereupon designated an infant. (Hereafter, the term "fetus" will refer to a living fetus unless otherwise specified.)

"Viable infant" refers to an infant likely to survive to the point of sustaining life independently, given the support of available medical technology. This judgment is made by a physician.

"Possibly viable infant" means the fetus *ex utero* which has not yet been determined to be viable or nonviable. This is a decision to be made by a physician. Operationally, the physician may consider that an infant with a gestational age of 20 to 24 weeks (five to six lunar months; four and one-half to five and one-half calendar months) and a weight between 500 to 600 grams may fall into this indeterminate category. These indices depend upon present technology and should be reviewed periodically.

"Nonviable fetus" refers to the fetus *ex utero* which, although it is living, cannot possibly survive to the point of sustaining life independently, given the support of available medical technology. Although it may be presumed that a fetus is nonviable at a gestational age less than 20 weeks (five lunar months; four and one-half calendar months) and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance. The Commission is not aware of any well-documented instances of survival of infants of less than 24 weeks (six lunar months; five and one-half calendar months) gestational age and weighing less than 600 grams; it has chosen lower indices to provide a margin of safety. These indices depend upon present technology and should be reviewed periodically.

"Dead fetus" *ex utero* refers to a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of umbilical cord (if still attached). Generally, some organs, tissues and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.

"Fetal material" refers to the placenta, amniotic fluid, fetal membranes and the umbilical cord.

"Research" refers to the systematic collection of data or observations in accordance with a designed protocol.

"Therapeutic research" refers to research designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods that depart from standard medical practice but hold out a reasonable expectation of success.

"Nontherapeutic research" refers to research not designed to improve the health condition of the research subject by prophylactic, diagnostic or treatment methods.