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Fetal Research--The Legislative Answer

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FETAL RESEARCH—THE LEGISLATIVE ANSWER

Fetal research is an active research area and, with the liberalization of abortion laws after the Supreme Court decision in Roe v. Wade, is a growing area. The future of research involving human fetal organs and tissues is currently in jeopardy because of state legislative attempts to place severe restrictive limitations on this type of study and because such attempts conflict with the federal regulations governing federally funded fetal research. Regulations governing fetal research are directed towards activities involving the fetus in the uterus (in utero), the viable fetus outside the uterus (ex utero), the nonviable fetus ex utero, and the dead fetus. There is no uniformity between the state laws governing fetal experimentation and the federal regulations allowing specific types of fetal research. These differences put the medical researcher in a precarious position. While it would appear that the researcher in a state with no state statute governing fetal experimentation may continue research under a private grant without any regulation or fear of reprisal, a researcher in a state with more restrictive statutes is not free to continue with a federally funded fetal research program without fear of state criminal charges.

I. FETAL EXPERIMENTATION

To gain some insight into the current controversies over fetal experimentation one must examine some of the research on live fetuses which has been conducted. Experimentation on the fetus

in utero is not necessarily directed towards preserving the life of that particular fetus, nor does it always involve the treatment of that particular fetus. Results of fetal experimentation in utero have enabled the traditional method of the use of x-ray in prenatal diagnosis to be supplemented by amniocentesis, ultrasound, fetoscopy, and fetal blood sampling. Intrauterine blood transfusions have been employed for several years for Rh incompatibility and more recently attempts have been made to treat fetal lung immaturity prenatally. Studies on fetal behavior and numerous retrospective studies concerning the effect on the fetus of drugs administered to the mother for therapeutic reasons have been done. Prospective studies have been performed prior to abortion, including two rubella vaccine studies to determine whether the vaccine would deform the fetus. Studies on the fetus in utero, a few hours or days prior to abortion, have been performed to test new techniques of prenatal diagnosis. Nutritional experiments and experiments of abortion techniques have been studied on the fetus prior to abortion. Numerous experiments have been performed to study placental transfer. During the abortion procedure, the fetus has been studied to investigate whether a com-

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16 Philipson, Sabath, and Charles, *Transplacental Passage of Erythromycin*
pound introduced on the fetal side of the placenta enters the maternal blood stream. Other studies have investigated fetal metabolism during the abortion procedure.

The fetus outside the uterus has been used to study fetal metabolism, since the aborted fetus may continue to live for a period of time although clearly not viable. One study involved the decapitation of eight aborted fetuses to measure cerebral oxidation of glucose metabolites. Many studies involve the use of fetal organs to follow studies commenced prior to abortion. Other studies on nonviable fetuses have been used to study life prolongation of the fetus. Thymuses from live nonviable fetuses have been transplanted into infants suffering from "Swiss type" agammaglobulinaemia.

Fetal research is many things. Some experiments are for the benefit of the fetus; however, the controversial experiments are those which are accomplished by procedures which are neither established and accepted methods of treatment nor intended to benefit the fetus involved. The fetus is living and life does command respect, but the United States Supreme Court absolved itself of any obligation to protect the life of the early fetus by declining to recognize the fetus as a person. The decision in Roe v. Wade focused on the mother's right during the first trimester of pregnancy by allowing the mother to have the fetus removed from her womb, but offered no guide as to what procedure was proper conduct in removing the fetus or how the fetus was to be treated once

\[ \text{and Clindamycin, } 288 \text{ New Eng. J. Med. 1219 (1973); } \text{Indänpää-Hiikkila et al., Elimination and Metabolic Effects of Ethanol in Mother, Fetus, and Newborn Infant, } 112 \text{ Am. J. Obstet. Gynecol. 387 (1972).} \]


out of the womb. It is with these unanswered questions that the current controversies over fetal research now lie.

II. Federal Regulations

On July 12, 1974, the National Research Act\textsuperscript{24} was signed into law. Section 201\textsuperscript{25} of the Act created a Commission to be composed of eleven members appointed by the Secretary of the Department of Health, Education, and Welfare. The members were to be selected from individuals distinguished in fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs. Not more than five of the members of the Commission could be individuals who were engaged in biomedical or behavioral research involving human subjects.

One of the Commission's duties was to "conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research [had] been undertaken, and alternative means for achieving such purposes."\textsuperscript{26} After the completion of the study the Commission was to "recommend to the Secretary policies defining the circumstances (if any) under which such research may be conducted or supported."\textsuperscript{27} The Act provided that until the Commission made its recommendations, the Secretary was prohibited from conducting or supporting research in the United States or abroad on a living human fetus, before or after an induced abortion, unless the purpose of the research was to assure the survival of the fetus involved.\textsuperscript{28}

After considering both the public comment and the recommendations of the Commission concerning the proposed rule to provide further protective measures for the fetus and the abortus as subjects of research activities, the Secretary amended the Public Health Service Act Regulations\textsuperscript{29} by adding a subpart governing research activities on the fetus and then lifted the moratorium on fetal research.\textsuperscript{30} The regulations issued by the Secretary apply to all Department of Health, Education, and Welfare grants and contracts\textsuperscript{31} supporting research, development, and related activities.
involving: (1) the fetus, (2) pregnant women, and (3) human in vitro fertilization.\textsuperscript{32} The regulations further provide that compliance with the procedures does not render inapplicable pertinent state or local laws bearing upon activities covered by the regulations.\textsuperscript{33}

The pertinent parts of the regulations dealing with fetal research are: (1) activities directed toward fetuses in utero as subjects,\textsuperscript{34} (2) activities directed toward fetuses ex utero including nonviable fetuses, as subjects\textsuperscript{35} and (3) activities involving the

\textsuperscript{32} HEW Reg. § 46.201(a), 40 Fed. Reg. 33525, 33528 (1975).

\textsuperscript{33} Id. § 46.201(b).

\textsuperscript{34} (a) No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

\textsuperscript{35} Id. at 33529 § 46.209.

(a) No fetus ex utero may be involved as a subject in an activity covered by this subpart until it has been ascertained whether the particular fetus is viable, unless: (1) There will be no added risk to the fetus resulting from the activity, and (2) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless: (1) 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, (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.

(c) In the event the fetus ex utero is found to be viable it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.
dead fetus, fetal material, or the placenta.36

III. STATE STATUTES REGULATING FETAL EXPERIMENTATION

Fifteen states have enacted statutes dealing with fetal experimentation.37 Some allow the researcher to follow federal guidelines for fetal experimentation while others put the researcher in danger of state criminal charges if he chose to follow federal guidelines.38

A. Fetuses in utero

Seven of the state statutes deal with the highly controversial area of activities directed toward the fetus in utero.39 Utah prohibits all experimentation with the unborn child except when advisable in the best medical judgment of the physician to determine genetic defects.40 Massachusetts and North Dakota do not prohibit procedures incident to the study of the fetus in utero provided the procedures do not substantially jeopardize the life or health of the fetus and the fetus is not the subject of a planned abortion, nor do their statutes specifically prohibit or regulate diagnostic or reme-

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

Id. at 33530 § 46.209.41

36 "Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities." Id. at 33530 § 46.210.

37 See note 2 supra.

38 Federal regulations provide that compliance with federal procedures does not render inapplicable state laws covering fetal research. HEW Reg. § 46.201(b), 40 Fed. Reg. 33525, 33528 (1975). A person convicted for violation of the Louisiana fetal research statute can be sentenced to five to twenty years at hard labor or fined not more than ten thousand dollars or both. LA. REV. STAT. ANN. § 14:87.2 (West 1974). See note 43 infra.


40 "Experimentation with unborn children prohibited-testing for genetic defects: Live unborn children may not be used for experimentation, but when advisable, in the best medical judgment of the physician may be tested for genetic defects." Utah Code Ann. § 76-7-310 (Supp. 1975).
dial procedures used to determine the life or health of the fetus or to preserve the life or health of the fetus. Maine prohibits any form of experimentation on the fetus in utero. Louisiana forbids

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41 No person shall use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory, research or other kind of experimentation. This section shall not prohibit procedures incident to the study of a human fetus while it is in its mother's womb, provided that in the best medical judgment of the physician, made at the time of the study, said procedures do not substantially jeopardize the life or health of the fetus, and provided said fetus is not the subject of a planned abortion. In any criminal proceeding the fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the study, that she was not planning an abortion.

This section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved or the mother involved.

A fetus is a live fetus for purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development.

No experimentation may knowingly be performed upon a dead fetus unless the consent of the mother has first been obtained, provided however that such consent shall not be required in the case of a routine pathological study. In any criminal proceeding, consent shall be conclusively presumed to have been granted for the purposes of this section by a written statement, signed by the mother who is at least eighteen years of age to the effect that she consents to the use of her fetus for scientific, laboratory, research or other kind of experimentation or study; such written consent shall constitute lawful authorization for the transfer of the dead fetus.

No person shall perform or offer to perform an abortion where part or all of the consideration for said performance is that the fetal remains may be used for experimentation or other kind of research or study.

No person shall knowingly sell, transfer, distribute or give away any fetus for a use which is in violation of the provisions of this section. For purposes of this section, the word "fetus" shall include also an embryo or neonate.

Whoever violates the provisions of this section shall be punished by imprisonment in a jail or house of correction for not less than one year nor more than two and one half years or by imprisonment in the state prison for not more than five years.


42 Whoever shall use, transfer, distribute or give away any live human fetus, whether intrauterine or extrauterine, or any product of
all in utero experimentation "except to preserve the life or improve the health" of the fetus. The Minnesota statute appears to allow experimentation on the fetus in utero if the procedure has been shown to be harmless by verifiable scientific evidence; however, the statute only speaks of the living conceptus without reference to in utero or ex utero. South Dakota has the most liberal of all fetal experimentation statutes, requiring only that the mother's consent be obtained. Eight statutes specifically prohibit exper-
mentation on the aborted fetus without reference to the fetus in utero; the question arises as to whether these eight states implicitly permit experimentation on the fetus in utero without any regulation.

The purpose of such legislation is certainly to quiet people's fears of the about-to-be-aborted fetus becoming nothing more than the object of experimentation. However, it does not seem rational to permit use of a procedure to determine the health of a fetus when those results may be used in the decision of whether to terminate a pregnancy by abortion, and to not permit research which might some day prevent the formation of congenital abnormalities or fetal deaths. 47

The Commission urged that research activities directed toward the health care of the fetus in utero be encouraged rather than restricted. 48 However, concern was expressed regarding research which was not related to health care, fearing that the fetus might become an experimental object, particularly when termination of the pregnancy was a factor. 49 In dealing with this problem, the federal regulations reflect the importance of the knowledge to be gained from research in this area and allow experimentation when the risk imposed by the research is minimal and the purpose is the development of biomedical knowledge that cannot be obtained by any other method. 50

B. Fetus ex utero, viable and nonviable

There should be no controversy over experimentation on the viable fetus. The viable fetus should be treated as a premature infant and accorded the same rights. The South Dakota statute, however, requires only the consent of the mother for fetal experimentation and on its face would appear to include the viable fetus. 51 Utah prohibits in utero fetal experimentation making no mention of ex utero fetal experimentation. 52 Utah requires that if

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47 See note 40 supra.
49 Id.
50 See note 34 supra.
51 See note 45 supra.
52 See note 40 supra.
there is any reasonable possibility that the unborn child could survive outside the mother's womb, the abortion procedure used must be one which will give the child the best chance of survival. Due to this section, more live nonviable fetuses will be delivered; however one point left unclear is whether the exclusion of experimentation on unborn children implicitly gives permission for experimentation on the fetus ex utero.

Most state statutes do not deal with the live fetus in terms of viable and nonviable. Exceptions are Kentucky and Nebraska, which prohibit all experimentation on any "live or viable" aborted child. Maine prohibits all ex utero experimentation on live fetuses. Illinois, Indiana, and Ohio forbid all ex utero experimentation without reference to the fetus being viable, nonviable,

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53 "If an abortion is performed when the unborn child is sufficiently developed to have any reasonable possibility of survival outside its mother's womb, the medical procedure used must be that which, in the best medical judgment, will give the unborn child the best chance of survival." UTAH CODE ANN. § 76-7-307 (Supp. 1975).

54 "Whoever shall sell, transfer, distribute or give away any live or viable aborted child or permits such child to be used for any form of experimentation shall be imprisoned in the penitentiary for a term of not less than ten (10) nor more than twenty (20) years . . . ." KY. REV. STAT. ANN. § 436.026 (Cum. Supp. 1974).

55 Whoever shall sell, transfer, distribute, or give away any live or viable aborted child for any form of experimentation shall, upon conviction thereof, be punished by a fine of not more than one thousand dollars, or by imprisonment in the county jail not more than one year, or by both such fine and imprisonment. Any person consenting, aiding, or abetting such sale, transfer, distribution, or other unlawful disposition of an aborted child shall be punished by a fine of not more than one thousand dollars, or by imprisonment in the county jail not more than one year, or by both such fine and imprisonment.


56 See note 42 supra.

57 "All tissue removed at the time of abortion shall be submitted for analysis and tissue report to a board eligible or certified pathologist as a matter of record in all cases. There shall be no exploitation of or experimentation with the aborted tissue." ILL. ANN. STAT. ch. 38, § 81-18 (Supp. 1975).

58 No experimentation except pathological examinations shall be conducted on any fetus aborted under this chapter (§§ 10-107-10-114), nor shall any fetus so aborted be transported out of this state for experimental purposes. Whoever conducts such an experiment or so transports such a fetus shall be guilty of a misdemeanor . . . .


59 "No person shall experiment upon or sell the product of human conception which is aborted. Experiment does not include autopsies pursuant to sections 313.13 and 2108.50 of the Revised Code." OHIO REV. CODE ANN. § 2919.14(A) (1975).
or dead. California, Louisiana, Massachusetts, Montana, North Dakota, and Pennsylvania forbid all ex utero experimentation on live fetuses, except to preserve the life or health of the fetus. The Minnesota statute, which appears to apply equally to the fetus ex utero and in utero, allows for experimentation which has been shown to be harmless.

Most of the state regulations prohibit experimentation on live fetuses. There is little doubt that from the definitions given with the state statutes that the term "live fetus" includes both the viable and the nonviable fetus. The federal regulations divide the live fetus into two classes, viable and nonviable. The viable fetus is one that after spontaneous or induced delivery is able to "survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration." The non-

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68 It is unlawful for any person to use any aborted product of human conception, other than fetal remains, for any type of scientific or laboratory research or for any other kind of experimentation or study except to protect or preserve the life and health of the fetus. "Fetal remains," as used in this section, means a lifeless product of conception regardless of the duration of pregnancy. A fetus shall not be deemed to be lifeless for the purposes of this section, unless there is an absence of a discernible heartbeat.

CALIF. HEALTH AND SAFETY CODE ANN. § 25956(a) (Deering 1975).
69 See note 43 supra.
70 See note 41 supra.
71 "No person may use any premature infant born alive for any type of scientific research, or other kind of experimentation except as necessary to protect or preserve the life and health of such premature infant born alive." MONT. REV. CODE ANN. § 94-5-617(3) (Int. Supp. 1974).
72 See note 41 supra.
73 "No person shall use any premature infant aborted alive for any type of scientific, research, laboratory, or other kind of experimentation except as necessary to protect or preserve the life and health of such premature infant aborted alive." PA. STAT. ANN. tit. 35, § 6605(b) (Supp. 1975).
74 See note 44 supra.
75 See, e.g.:
"Liveborn" and "live birth" as used in sections 1574 and 1575, shall mean a product of conception after complete expulsion or extraction from its mother, irrespective of the duration of pregnancy, which breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered live born and fully recognized as a human person under Maine law.

viable fetus *ex utero* is one which "although living, is not viable." The dead fetus is one "which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached)."

The federal regulations allow limited experimentation on the nonviable fetus. The Secretary made an exception to the recommendations of the Commission in regard to fetal experimentation on the nonviable fetus for the purpose of permitting research to develop new methods for enabling increasingly small fetuses to survive to the point of viability and to allow the development of important biomedical knowledge which cannot be obtained by animal experimentation or by any other means. The Secretary may, however, take into account medical advances in determining whether a fetus is viable.

Research on a live fetus that will inevitably die, regardless of whether the research is done, is perhaps the most emotional area of fetal research. However, if research is not done on the unwanted nonviable fetus, it will be done on the wanted fetus. Everytime a new drug, a new operative procedure, or new vaccine is utilized on a human subject an experiment is being performed.

**C. Fetal material, the dead fetus or the placenta**

The Commission thought it unnecessary to draft legislation governing research on the dead fetus because such research would be governed in part by the Uniform Anatomical Gift Act which has been adopted by forty-nine states, and because any relevant state or local law would be applicable. Indiana, however, has adopted a statute that prohibits any experimentation on any dead fetus aborted under the state abortion law. The Ohio statute prohibits experimentation upon "the product of human conception which is aborted." The Illinois statute states that "[t]here shall be no

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10 *Id.* § 46.203(e).
11 *Id.* § 46.203(f).
12 *See* note 35 *supra*.
13 *See* discussion on activities directed toward fetuses *ex utero* as subjects. 40 Fed. Reg. 33525, 33528 (1975).
14 *See* note 35 *supra*.
16 *See* discussion on activities directed toward the dead fetus. *Id.* at 33528.
17 *See* note 58 *supra*.
18 *See* note 59 *supra*.
exploitation of or experimentation with the aborted tissue.”\textsuperscript{78} Massachusetts,\textsuperscript{79} North Dakota,\textsuperscript{80} and South Dakota\textsuperscript{81} require only that the mother’s consent be obtained before experimentation on the dead fetus. California specifically allows experimentation on the dead fetus or the lifeless product of abortion.\textsuperscript{82}

The wisdom of legislation proscribing experimentation on dead fetuses is questionable. The dead fetus as any other dead human is not a person. However, a dead fetus does command respect and this limits what one feels permitted to do with it. Nevertheless, to “allow the dead products of abortion a privilege and dignity beyond those of the dead body is irrational and offensive, as long as we permit autopsy and exploitation of parts of the human body.”\textsuperscript{83}

IV. LEGISLATIVE SUGGESTIONS

Because of the important knowledge to be gained, all fetal research should not be banned; however, before legislation is drafted to regulate fetal experimentation, great care must be taken not only to protect the fetus, but also the researcher. The language of most of the statutes is so broad that it is incapable of strict interpretation, and many statutes are so vague that the researcher has no way of knowing what types of experimentation are allowed.\textsuperscript{84}

All proposed legislation must take into account activities directed toward the fetus in utero. Those statutes which specifically and solely exclude research on any aborted product impliedly per-

\textsuperscript{78} See note 57 supra.
\textsuperscript{79} See note 41 supra.
\textsuperscript{80} Id.
\textsuperscript{81} See note 45 supra.
\textsuperscript{82} See note 60 supra.
\textsuperscript{83} W. Gaylin, Fetal Politics: The debate on experimenting with the unborn, 235 THE ATLANTIC MONTHLY 66, 69 (May 1975).
\textsuperscript{84} In Massachusetts where fetal researchers worked with the legislative group drafting the fetal experimentation statute, the law was thought to be a moderate and enlightened law. It soon became clear that the scientists did not understand the law and ironically those same scientists who worked to be sure the law would allow their research project on prenatal diagnosis of genetic blood diseases to continue were turned down by the human experimentation committee at Harvard University-affiliated Boston Hospital for Women on a project designed to improve the aminioscope used in their work. Culliton, Fetal Research (III): The Impact of a Massachusetts Law, 187 SCI. 1175, 1176 (1975).
mit research on the fetus in utero and leave the fetus unprotected. More importantly, those statutes which flatly prohibit all in utero research could restrict the doctor in using prenatal diagnostic techniques necessary to the health of the fetus. Although experimentation on the fetus prior to a planned abortion prevents the pregnant woman from changing her mind without fear of delivering an injured child, the benefits of valuable scientific knowledge accruing to a wanted fetus must also be considered. Legislation in this area must not preclude experimentation that is directed toward the health care of the fetus. Where the risk is minimal to the about-to-be aborted fetus and the purpose of the experiment is to gain important biomedical knowledge that cannot be obtained by any other means, careful thought must be given to the value of such experimentation before totally restricting in utero fetal experimentation to those instances where experimentation is required to preserve the life and health of the fetus.

Legislation dealing with the fetus ex utero must cover the viable, nonviable, and dead fetus. To treat all fetuses as "live" and restrict experimentation on all live products of abortion can lead to unwanted results. There should be no controversy over legislation dealing with the viable fetus. To restrict experimentation on the live products of abortion may force the physician to try to preserve the life of the fetus by conventional, nonexperimental methods when a more flexible statute would enable the physician to try to save the life of the fetus by unconventional or experimental procedures. The physician must be able to act in the best possible way to preserve the life and health of the fetus. The viable fetus from an induced abortion should not be treated differently than the viable fetus from a spontaneous abortion. No statute should be so vague as to implicitly allow experimentation other than experiments to preserve the life and health of the aborted viable fetus or to deny it the rights of a premature infant.

In determining if experimentation on the nonviable fetus should be allowed, one must consider the importance of the specific research project and the benefit to be gained by the wanted fetus. The Secretary recognized the need for the development of procedures on nonviable fetuses to bring viability to increasingly small fetuses. See note 35 supra.
viable fetus when there will be no added risk to the fetus and the purpose is to gain important knowledge that cannot be obtained elsewhere. If research on nonviable fetuses is to be permitted, the legislation must give careful attention to the definitions of viability and nonviability and provisions included for changing the definitions with advances in medical science.

There is no reason for any legislation covering the dead fetus, fetal material, or the placenta if the state has adopted the Uniform Anatomical Gift Act. There is no rational reason to offer more protection to the fetus obtained by an induced abortion than the fetus obtained by a spontaneous abortion or the dead human adult.

There are many other considerations that must be dealt with in legislation governing fetal research. Consent to the experiments presents a problem with no absolute answer, but must be included in all aspects of fetal research. In formulating the federal regulations, the Commission agreed that a pregnant woman’s decision to terminate her pregnancy by abortion does not create the presumption that she lacks interest in the fetus and, thus, requires her consent and the father's, if he is known, for all experimentation. The general limitations set forth in the federal regulations require that appropriate animal studies be completed, that the risk to the fetus be minimal, that individuals engaged in the activities have no part in the abortion decision or in determining the viability of the fetus, and that no money be offered to terminate a pregnancy for research purposes.

Id.


(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal
The fear of the "abortus" becoming an object of unlimited experimentation has caused statutes regulating fetal experimentation to be included in abortion statutes that were amended after the Roe v. Wade decision. West Virginia has not amended its abortion statute although it is clearly unconstitutional. When the abortion statute is amended, statutes regulating fetal experimentation should not be included. Fetal experimentation statutes should not differentiate the product of an induced abortion from the product of spontaneous abortion because one should not receive more protection than the other. Separate, well written statutes covering fetal experimentation should alleviate the fear of the "abortus" becoming an experimental object.

Once standardized guidelines are established by the legislature to regulate fetal research, the individual researcher cannot be left to determine at his peril if his project fits within the framework of the regulations. A board must be established to review all research proposals to determine if all aspects of the activity are covered by the regulations. This board should be a statewide commission or an institutional group such as those that approve other human research activities. Care must be taken that the members risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity. (b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

10 410 U.S. 113 (1973).
13 In response to federal requirements for Public Health Service supported grants, West Virginia University submitted a statement of Institutional Assurance on Investigations Involving Human Subjects, including Clinical Research to the United States Public Health Service. A review committee which was included in the plan was constituted as follows: (1) one senior member of one of the clinical departments of the School of Medicine; (2) one senior member of one of the departments of basic health science within the Medical Center; (3) when University Hospital patients, facilities or personnel were concerned, the Director of the University Hospital or his designee; and, (4) additional persons chosen from senior members of the faculty of any appropriate unit of the University to make a committee of five to seven members. The review committee was to review plans of investigation involving human subjects prior to initiation of such plans. (Letter from Harry B. Heflin, Acting President to Chief, Division of Research Grants, Nov. 4, 1966, on file with author.) With minor changes the plan was approved by the United States Public Health Service. (Letter from Stephen B. Hatchett, Acting Director, Division of Research Grants to Harry B. Heflin, Acting President, Jan. 13, 1967,
are capable of dealing with the medical, legal, social, ethical, and related issues.

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on file with author.) The review committee has functioned under the guidelines of the Assurance, with minor changes to meet new federal requirements, to review not only applications for Public Health Service Grants but all research involving human subjects throughout the University.