fields, and governmental jurisdictions with populations of less than 50,000.

This action will not have a significant economic impact on a substantial number of small entities because the original requirements did not have a significant effect on a substantial number of small entities. The extension on the suspension does not change those original requirements. Any future regulatory action on this issue will address any economic impacts, including impacts on small entities.

Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this extension to a suspension of a final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This action does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

We have analyzed this action under E.O. 13132 and have determined that it does not have implications for federalism under that Order. Because this action extends a suspension of a final rule, it does not preempt any state action.

Unfunded Mandates Reform Act

This action will not result in an unfunded mandate under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538).

Taking of Private Property

This action will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that preparation of an Environmental Impact Statement is not necessary. An Environmental Assessment and a Finding of No Significant Impact are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 155

Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

1. The authority citation for part 155 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j); 46 U.S.C. 3715, 3719; sec. 2, E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; 49 CFR 1.46, 1.46 (iii).

Sections 155.110–155.130, 155.350–155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), and 155.1065(g) also issued under 33 U.S.C. 1903(b); and §§ 155.1110–155.1150 also issued 33 U.S.C. 2735.

Note: Additional requirements for vessels carrying oil or hazardous materials appear in 46 CFR parts 30 through 36, 150, 151, and 153.

§ 155.1050 [Amended]

2. In § 155.1050, paragraph (k)(3) is suspended until February 12, 2004.

§ 155.1052 [Amended]

3. In § 155.1052, the last sentence in paragraph (f) is suspended until February 12, 2004.

Dated: January 10, 2001.

R.C. North,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 01–1205 Filed 1–11–01; 2:28 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICE

45 CFR Part 46

RIN 0925–AA14

Protection of Human Research Subjects

AGENCY: Department of Health and Human Services (DHHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (DHHS) is amending its human subjects protection regulations. These regulations provide additional protections for pregnant women and human fetuses involved in research and pertains to human in vitro fertilization. The rule continues the special protections for pregnant women and human fetuses that have existed since 1975. The rule enhances the opportunity for participation of pregnant women in research by promoting a policy of presumed inclusion, by permitting the pregnant woman to be the sole decision maker with regard to her participation in research, and by exempting from the regulations six categories of research. The rule also provides a mechanism for the Secretary of HHS to conduct or fund research not otherwise approvable after consultation with an expert panel and public review and comment.

DATES: Effective date: March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Susan Sherman, JD, Office for Human Research Protections (OHRP), 6100 Executive Blvd, Suite 3B01, Rockville, MD 20892–7507. Telephone 301–496–7005. Email: *ShermanS@od.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by the agency through regulations codified at Title 45, part 46, of the Code of Federal Regulations. Subpart B of 45 CFR part 46, promulgated on August 8, 1975, pertains to research involving fetuses, pregnant women, and human in vitro fertilization. The 1975 regulations were jointly published in the **Federal Register** with the report and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research on the Fetus (40 FR 33526). Subsequent changes were incorporated January 11, 1978 (43 FR 1758), November 3, 1978 (43 FR 51559), and June 1, 1994 (59 FR

28276). This preamble refers to these rules as the ''1975 regulations.''

Recent guidelines issued by components of DHHS have addressed the participation of women in research as follows:

- Food and Drug Administration 1993 Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (58 FR 39406);
- National Institutes of Health 1994 Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (59 FR 14508); and
- Centers for Disease Control and Prevention 1995 Policy on the Inclusion of Women and Racial and Ethnic Minorities in Externally Awarded Research (60 FR 47947), and February 16, 1996 policy Inclusion of Women and Racial and Ethnic Minorities in Research.

These policies are all designed, in part, to improve the opportunity for women to be included as subjects in research.

A Committee on the Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies of the Institute of Medicine issued a report in 1994 on Women and Health Research that included the recommendation that DHHS revise subpart B in accordance with the Committee's other recommendations. The Committee believed that women and men should have the opportunity to participate equally in the benefits and burdens of research, and many of the Committee's recommendations were aimed at enhancing the participation of women, including pregnant women, in clinical research.

The National Task Force on AIDS Drug Development and the Presidential Advisory Council on HIV/AIDS subsequently recommended that the lack of paternal consent should not disqualify a pregnant woman from participation in a federally funded clinical trial.

These guidelines and recommendations, and the lack of a formal review of subpart B for over two decades, led DHHS to determine that a substantive examination of subpart B was appropriate.

Based on this review the Department proposed to amend subpart B in a Notice of Proposed Rulemaking (NPRM) published on May 20, 1998 (63 FR 27794). The Department proposed that a policy of presumed opportunity for inclusion of pregnant women in research replace one of presumed exclusion. The Department also concurred with the recommendations of the National Task Force on AIDS Drug Development, the Presidential Advisory Council on HIV/AIDS, and the IOM Committee regarding paternal consent and proposed to modify the consent requirement to remove potential barriers to research that might provide a medical benefit to a fetus.

The exemptions in 45 CFR part 46, Subpart A, Basic DHHS Policy for Protection of Human Research Subjects, were proposed to apply to subpart B. These exemptions of certain categories of research (*e.g.*, survey research without subject identifiers) have applied since 1981 to research involving nonpregnant women.

In light of the 1993 legislative nullification of the regulatory requirement for ethical advisory board review of research involving in vitro fertilization of human ova (Public Law 103–43), the Department proposed a mechanism for the Secretary to modify or waive certain requirements of Subpart B, following consultation with experts and public input, in place of the provision that the Department have a standing ethical advisory board. Nonsubstantive technical, formatting, and clarifying changes were also proposed.

Discussion of Comments

During the public comment period that ended August 18, 1998, the Department received 13 public comments on the proposed rule from interested parties. The comments are summarized as follows:

General Comments

One commenter endorsed the NPRM in its entirety. One commenter suggested that there be three classes of research that mirror the categories in subpart D of part 46, Additional DHHS Protections for Children Involved as Subjects in Research. Those categories are: no greater than minimal risk, greater than minimal risk but presenting the prospect of direct benefit, and greater than minimal risk and no prospect of direct benefit. The Department finds that modification of the format of subpart B to parallel the categories of research in subpart D would not enhance the protection of women or fetuses and would likely cause confusion. Subpart B, since its inception in 1975 and in this final rule, requires that the risk to the fetus be the least possible risk for achieving the research objectives and any risk which is greater than minimal must hold out the prospect of direct benefit for the fetus or the woman.

One commenter objected to distinctions between ''therapeutic'' and ''nontherapeutic'' research as illogical, because, by definition, the purpose of research is always to contribute to generalizable knowledge. The commenter noted that this distinction confuses therapy with research. The Department concurs with this comment and has modified the final rule to eliminate language implying that the purpose of research is ever therapeutic. The final rule uses the phrases ''* * * interventions or procedures that hold out the prospect of direct benefit * * *'' and ''* * * research [that] holds out the prospect of enhancing the probability of survival * * *'' to describe research from which a subject may benefit (§ 46.204(b) and § 46.205(b)(1)(i)).

Applicability (Section 46.201)

The Department proposed that the exemptions at 45 CFR 46.101(b)(1)–(6) of subpart A apply to subpart B. These exemptions of six categories of research were promulgated in 1981, subsequent to the last substantive revision of subpart B, and have applied to research with nonpregnant subjects since that time. Two commenters endorsed the incorporation of the exemptions into subpart B. One commenter noted that pregnancy should not preclude women from participating in these types of research; one stated that pregnant women are autonomous decision makers and should not be treated as vulnerable or impaired because of their condition. Consistent with these comments, the exemptions are retained in the final rule (§ 46.201(b)).

The Department has retained in the final rule language specifying that the requirements of subpart B are in addition to those imposed under the other subparts of 45 CFR part 46, for purposes of clarity (§ 46.201(d)).

Definitions (Section 46.202)

The proposed definitions were substantively the same as those in the 1975 regulations.

The Department proposed the following simplified definition of ''fetus:'' ''fetus means the product of conception during pregnancy until a determination is made after delivery that it is viable.'' One commenter noted that ''product of conception'' is generally understood to mean the associated placenta as well. The Department intends that research with the placenta prior to delivery be governed by 45 CFR 46.204, Research involving pregnant women or fetuses prior to delivery. For purposes of clarity, the definition of ''fetus'' in the final rule utilizes the phrase ''from implantation,'' which is the same phrase used in the definition of ''pregnancy.''

Since 1975, subpart B has included the fetus *ex utero* until such time as

viability of the fetus is determined. The Department proposed to replace the phrase ''ex utero'' with ''after delivery.'' No comments were received on that proposal and the final rule retains the proposed language.

The Department also proposed the term ''newborn,'' equating newborn with ''fetus after delivery,'' because some persons may prefer one term to the other depending on the length of the gestation period. Two commenters found the introduction of this term confusing and inconsistent because after delivery there exists an entity that could be called either fetus or newborn. The Department concurs with these comments and has deleted the term ''newborn'' from the final rule.

One commenter noted that newborns can be of any species and believed that the term ''child'' should be used in place of ''newborn.'' Another commenter stated that a viable fetus is generally understood to mean a fetus after the point of viability, generally at 5–6 months gestation. In response to these comments the Department has defined ''viable'' in the final rule and emphasized that, as it pertains to the fetus, ''viable'' means a fetus after delivery and the regulations at 45 CFR part 46, subpart D, are applicable (§ 46.202(h)).

Research Involving Pregnant Women or Fetuses Prior to Delivery (Section 46.204)

For purposes of clarity, the scope of § 46.204 has been narrowed in the final rule to research involving pregnant women or fetuses prior to delivery, and those provisions of proposed § 46.204 that are applicable to research involving fetuses after delivery have been repeated in section § 46.205 (see § 46.205(a)(1)–(6) and (b)(1)(i)).

The Department proposed to require, as a prerequisite to research on pregnant women or fetuses, preclinical and clinical studies, including studies on nonpregnant women, that provide data for assessing potential risks to pregnant women and fetuses. One commenter endorsed the increased specificity and noted that it would ensure that reproductive toxicity data are available. Another commenter found that to require pregnant women to wait until studies have been conducted on nonpregnant women is to neglect them as a population. The Department notes that preclinical and clinical studies are required only when scientifically appropriate. The final rule retains the proposed provision for preclinical and clinical studies (§ 46.204(a) and § 46.205(a)(1)).

To strengthen protections for the pregnant woman and fetus, the Department proposed a new informed consent provision: that the woman be fully informed regarding the reasonably foreseeable impact of the research on the fetus. No commenters objected to this provision. The final rule, at § 46.204(e), retains this requirement with the clarification that it also applies to the legally authorized representative. This provision is repeated in § 46.205(a)(2), so that the person whose informed consent is a prerequisite to participation in the research must be fully informed of the reasonably foreseeable impact of the research on the fetus.

One commenter stated that informed consent should highlight known or suspected risks and should incorporate unknown harms. The Department notes that provisions of subpart A at 45 CFR part 46.116(a)(2) and § 46.116(b)(1), respectively, also applicable to subpart B, address these concerns. The commenter further noted that researchers should work to ensure that the woman or her legally authorized representative understands the information that has been disclosed, that checks for understanding should be tailored according to the situation of particular women or representatives, and women should be encouraged to discuss research participation with their obstetrician before making a final decision about enrollment. The Department notes that ensuring that information is understood and checks for understanding tailored to particular situations are not precluded by the regulations, nor are they unique to research with pregnant women. Subpart A affords IRBs the opportunity and the authority to ensure the adequacy of informed consent and protections by imposing additional requirements or monitoring the research or the consent process. Similarly, with regard to the suggestion concerning encouragement of discussion with an obstetrician, the Department notes that the rules do not preclude encouragement to discuss participation with obstetricians or any other individuals and that subpart A requires that consent be sought only under circumstances that provide sufficient opportunity to consider participation (45 CFR 46.116).

The Department proposed to modify the consent requirements in the 1975 regulations by permitting research with pregnant women or fetuses prior to delivery based on the consent of the woman or her legally authorized representative. The Department recognizes and encourages paternal involvement in decisions affecting the pregnant woman and fetus prior to delivery. Nonetheless, in some cases the father's consent has been a barrier to participation in research of the woman or fetus prior to delivery. The recommendations of the National Task Force on AIDS Drug Development, the Presidential Advisory Council on HIV/AIDS, and the IOM Committee were unanimous that the consent of the father should not be a condition of the participation of a pregnant woman in research.

Ten commenters endorsed or applauded the proposal to modify the parental consent requirement, many describing specific research trials in which pregnant women were unable to participate in potentially beneficial research because of the requirement that the father's consent be secured. One commenter believed the consent of the father should continue to be required and that waivers from the Secretary should be sought if the father's consent is difficult to obtain. The Department concludes that the decision making authority for research participation of the pregnant woman or fetus prior to delivery should rest with the pregnant woman and has retained this provision in the final rule (§ 46.204(d)).

One commenter indicated that the rules are unclear whether a researcher may inform a pregnant woman of nonresearch alternatives. The Department notes that subpart B does not address alternatives to research, but that subpart A, at 45 CFR part 46.116(a)(4), also applicable to subpart B, requires disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

The Department has also decided to continue the use of the word ''terminate'' in sections 204 and 205 instead of utilizing the proposed change to the word ''abort.'' The Department believes that the original language is clearer.

Research Involving Fetuses After Delivery (Section 46.205)

As indicated above, those provisions proposed in § 46.204 that are applicable to research involving fetuses after delivery are reiterated in the final rule under § 46.205(a) and (b)(1)(i).

One commenter requested that the Department explain why this section is separate from subpart D. As noted above, the 1975 regulations extended the definition of fetus to include the fetus *ex utero* until such time as a fetus is determined to be viable. The final rule continues this extension because nonviable fetuses, and fetuses whose viability has not yet been determined

after delivery, require protection and are not covered by subpart D. Accordingly, subpart B permits research with fetuses of uncertain viability only if the research holds out the prospect of enhancing the probability of survival or there will be no risk resulting from the research and the purpose is the development of important biomedical knowledge that cannot be obtained by other means (§ 46.205(b)). Research with nonviable fetuses after delivery, which must be considered dying subjects, must meet the five criteria at § 46.205(c)(1)–(5), also intended to provide protection for such subjects.

Section 498(a), ''Fetal Research,'' of the Public Health Service Act, 42 U.S.C. 289g(a), places statutory restrictions on research involving nonviable living fetuses ex utero or living fetuses ex utero for whom viability has not been ascertained. The statute permits research under either of the following two conditions: ''the research * * * (1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or (2) will pose no added risk of suffering, injury, or death to the fetus and the purpose * * * is the development of important biomedical knowledge that cannot be obtained by other means.'' This rule exceeds those requirements for fetuses of uncertain viability by permitting research only if it either (1) holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, or (2) poses no risk to the fetus and the purpose is the development of important biological knowledge that cannot be obtained by other means. This rule also exceeds the statutory requirements for nonviable living fetuses ex utero by specifying that vital functions of the nonviable fetus may not be artificially maintained and the research may not terminate the heartbeat or respiration of the fetus.

The consent requirements for research involving fetuses of uncertain viability and nonviable fetuses at § 46.205(b)(2) and § 46.205(c)(5), respectively, also ensure protection of the fetus. Research involving fetuses of uncertain viability may proceed with the consent of either parent (or under certain circumstances the consent of a legally authorized representative), but the research must hold the prospect of enhancing the probability of survival of the fetus to the point of viability or pose no risk to the fetus. The Department recognizes that, in cases of uncertain viability, a decision regarding research participation must often be made very quickly, especially where the research presents the prospect of enhancing the probability of survival of the fetus. Thus, the consent of only one parent (or legally authorized representative) is required. However, if both parents are readily available at the time when a decision is needed, reasonable efforts should be made to provide all relevant information to both parents. The Department believes that research involving the nonviable fetus should only proceed with the consent of both parents (unless one is unavailable, incompetent, or temporarily incapacitated), and the consent of a representative is expressly prohibited. The individual(s) providing consent under § 46.205(b)(2) or (c)(5) must be fully informed regarding the reasonably foreseeable impact of the research on the fetus (§ 46.205(a)(2)).

Research after delivery, involving fetuses determined to be viable, is governed by Subpart D (§ 46.205(d)).

Research Not Otherwise Approvable That Presents Certain Opportunities section 46.207)

The Department proposed to replace the 1975 regulatory authority of the Secretary to modify or waive specific requirements with the approval of an ethical advisory board, with the authority to modify or waive requirements after consultation with appropriate experts and opportunity for public review and comment. The proposal would have required the Secretary to consider whether the risks to the subjects were so outweighed by the sum of the benefits to the subjects and the importance of the knowledge to be gained as to warrant modification or waiver. One commenter noted that the proposed waiver provision did not require IRB review, as does the similar section in subpart D (45 CFR 46.407). The commenter further noted that the proposed wording appeared to require that the overarching consideration be ''beneficence'' based, and that adopting the language in 45 CFR 46.407 would encompass all of the ethical principles in the Belmont Report and ensure consistency between subparts B and D. The Department concurs with these comments and the final rule, at § 46.207, is consistent with 45 CFR 46.407, with conforming and clarifying changes.

Under this provision the waiver authority is limited to the requirements of § 46.204 applicable to pregnant women and fetuses prior to delivery. The other requirements of subpart B, including those in § 46.205, cannot be waived. Even though the Secretary has the authority to waive the requirements of § 46.205 that exceed the statutory requirements of section 498(a), ''Fetal Research,'' of the Public Health Service Act, 42 U.S.C. 289g(a) (see discussion of § 46.205 above), it was determined that the additional protections afforded by § 46.205 are essential and should not be waived under any circumstances.

Conclusion

After considering the comments, the Department is adopting the rule as proposed except for the changes noted above and editorial changes to clarify the intent of the regulation. Distinctions between therapeutic and nontherapeutic research are eliminated. The term ''newborn'' is deleted in the final rule for purposes of clarity, and the definition of ''viable'' as it pertains to the fetus is clarified. Section 46.207, regarding approval by the Secretary of research that would not otherwise be approvable under § 46.204, is modified consistent with the similar provision in subpart D. The Department has also incorporated additional nonsubstantive editorial and clarifying revisions in the final rule.

The rule is effective 60 days after publication to give Institutional Review Boards (IRBs) time to incorporate the regulations into their review of research protocols. All initial and ongoing projects reviewed after the effective date by IRBs under Multiple Project Assurances or other Assurances with the DHHS, Office for Human Research Protections, OHRP (formerly OPRR), must be reviewed in accordance with these rules.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If an action is deemed to fall within the scope of the definition of the term ''significant regulatory action'' contained in § 3(f) of the Order, a pre-publication review by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) is necessary. OMB deemed this rule a ''significant regulatory action,'' as defined by Executive Order 12866. Therefore, the rule was submitted to OIRA for review prior to its publication in the **Federal Register**.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. Chapter 6) requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. This rule primarily affects individual research

subjects and institutions that receive funding from the Department of Health and Human Services for research involving human subjects. It will not have the effect of imposing significant additional costs on small research institutions that are within the definition of small entities. Therefore, the Secretary certifies that this rule will not have significant impact on a substantial number of small entities and that preparation of an initial regulatory flexibility analysis is not required.

Paperwork Reduction Act

This rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

List of Subjects in 45 CFR Part 46

Health—clinical research, medical research.

Dated: September 21, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

Approved: October 30, 2000.

Donna E. Shalala,

Secretary of Health and Human Services.

Accordingly, the Department of Health and Human Services amends part 46 of the Regulations for the Protection of Human Subjects (45 CFR part 46), as follows:

1. authority citation for 45 CFR part 46 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

2. Supbart B of 45 CFR part 46 is revised to read as follows:

Subpart B—Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization

Sec.

46.201 To what do these regulations apply?
46.202 Definitions.
46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization.
46.204 Research involving pregnant women or fetuses prior to delivery.
46.205 Research involving fetuses after delivery.
46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material.
46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses.

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women or human fetuses, and to all research involving the in vitro fertilization of human ova, conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of § 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in § 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Dead fetus* means a fetus after delivery that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(b) *Fetus* means the product of conception from implantation until a determination is made after delivery that it is viable.

(c) *In vitro fertilization* means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

(d) *Nonviable fetus* means a fetus after delivery that, although living, is not viable.

(e) *Pregnancy* encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(f) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(g) *Viable* as it pertains to the fetus means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus after delivery is viable then it is a child as defined by § 46.402(a), and subpart D of this part is applicable.

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§ 46.204 Research involving pregnant women or fetuses prior to delivery.

Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d);

(e) The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;

(f) For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(g) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(h) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(i) Individuals engaged in the research will have no part in determining the viability of a fetus.

§ 46.205 Research involving fetuses after delivery.

(a) After delivery, fetuses may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.

(2) The individual(s) providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child.

(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(4) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(5) Individuals engaged in the research will have no part in determining the viability of a fetus.

(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Fetuses of uncertain viability. After delivery, and until it has been ascertained whether or not a fetus is viable, a fetus may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research; and

(2) The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d).

(c) Nonviable fetuses. After delivery, a nonviable fetus may not be involved in research covered by this subpart unless all of the following additional conditions are met:

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

(2) The research will not terminate the heartbeat or respiration of the fetus;

(3) There will be no risk to the fetus resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the fetus is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.

(d) Viable fetuses. A fetus, after delivery, that has been determined to be viable is a child as defined by § 46.402(a) and may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the **Federal Register**, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d).

[FR Doc. 01–1122 Filed 1–16–01; 8:45 am]

BILLING CODE 4140–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–43, MM Docket No. 00–179, RM–9947]

Digital Television Broadcast Service; Arkadelphia, AR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Arkansas Educational Television Commission, licensee of noncommercial educational station KETG(TV), substitutes DTV *13 for DTV channel *46 at Arkadelphia. *See* 65 FR 59389, October 5, 2000. DTV channel *13 can be allotted to Arkadelphia in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (33–54–26 N. and 93–06–46 W.) with a power of 7.3, HAAT of 320.9 meters and with a DTV service population of 277 thousand. With is action, this proceeding is terminated.

DATES: Effective February 26, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report