State and county	Location and case No.	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community Number
Colorado: Larimer	City of Fort Collins (00–08–365P).	June 8, 2001, June 15, 2001, *Fort Collins Coloradoan*.	The Honorable Ray Martinez, Mayor, City of Fort Collins, P.O. Box 580, Fort Collins, Colorado 80522–0580.	August 23, 2001 ..	080102
Nevada: Clark	City of Mesquite (01–09–997P).	September 19, 2001, September 26, 2001, *Las Vegas Review-Journal*.	The Honorable Charles Home, Mayor, City of Mesquite, 10 East Mesquite Boulevard, Mesquite, Nevada 89027.	September 10, 2001.	320035
Nevada: Douglas	Unicorporated Areas (01–09–231P).	September 12, 2001, September 19, 2001, *Record Courier*.	Mr. Daniel C. Holler, County Manager, Douglas County, P.O. Box 218, Minden, Nevada 89423–0218.	August 16, 2001 ..	320008
Oregon: Multnomah.	City of Milwaukie (01–10–191P).	September 13, 2001, September 20, 2001, *The Oregonian*.	The Honorable Carolyn Tomei, Mayor, City of Milwaukie, 10722 Southeast Main Street, Milwaukie, Oregon 97222.	December 19, 2001.	410019
Oregon: Multnomah.	City of Portland (01–10–191P).	September 13, 2001, September 20, 2001, *The Oregonian*.	The Honorable Vera Katz, Mayor, City of Portland, 1221 Southwest Fourth Avenue, Suite 340, Portland, Oregon 97204.	December 19, 2001.	410183
Oregon: Multnomah.	Unincorporated Areas (01–10–191P).	September 13, 2001, September 20, 2001, *The Oregonian*.	The Honorable Diane Linn, Chairperson, Multnomah County Board of Commissioners, 501 Southeast Hawthorne Boulevard, Suite 600, Portland, Oregon 97214.	December 19, 2001.	410179
South Dakota: Union.	Unincorporated Areas (99–08–326P).	January 18, 2001, January 25, 2001, *Leader Courier*.	The Honorable Roger Boldenow, Chairman, Union County Board of Commissioners, P.O. Box 519, Elk Point, South Dakota 57025–0519.	December 28, 2000.	460242
Texas: Bexar	City of San Antonio (01–06–1953X).	September 27, 2001, October 4, 2001, *San Antonio Express News*.	The Honorable Edward D. Garza, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, Texas 78283–3966.	January 2, 2002 ...	480045
Texas: Dallas	City of Carrollton (00–06–1211P), (00–06–1214P), (00–06–1216P).	February 16, 2001, February 23, 2001, *Northwest Morning News (Formerly Metrocrest News)*.	The Honorable Milburn Gravley, Mayor, City of Carrollton, P.O. Box 110535, Carrollton, Texas 75011–0535.	May 24, 2001	480167
Texas: Lubbock	City of Lubbock	September 22, 2000, September 29, 2000, *Lubbock Avalanche*.	The Honorable Windy Sitton, Mayor, City of Lubbock, P.O. Box 491, Lubbock, Texas 79408.	December 28, 2000.	480452
Texas: Lubbock	City of Wolfforth (01–06–1799P).	September 27, 2001, October 4, 2001, *Lubbock Avalanche Journal*.	The Honorable Sylvia Preston, Mayor, City of Wolfforth, 382 East Highway 62, Wolfforth, Texas 79382.	September 5, 2001.	480918
Utah: Washington	City of Santa Clara (99–08–278P).	August 10, 2001, August 17, 2001, *The Spectrum*.	The Honorable Fred Rowley, Mayor, City of Santa Clara, P.O. Box 699, Santa Clara, Utah 84765.	November 15, 2001.	490178
Utah: Washington	City of St. George (99–08–278P).	August 10, 2001, August 17, 2001, *The Spectrum*.	The Honorable Daniel D. McArthur, Mayor, City of St. George, 175 East 200 North, St. George, Utah 84770.	November 15, 2001.	490177
Washington: Skamania.	City of North Bonneville (01–10–488P).	September 19, 2001, September 26, 2001, *Skamania County Pioneer*.	The Honorable John W. Kirk, Mayor, City of North Bonneville, P.O. Box 7, North Bonneville, Washington 98639.	September 13, 2001.	530256

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: October 29, 2001.

Robert F. Shea,

Acting Administrator, Federal Insurance and Mitigation Administration.

[FR Doc. 01–28393 Filed 11–9–01; 8:45 am]

BILLING CODE 6718–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0940–AA05

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 withdrawing Subpart B of its human subjects protection regulations published on January 17, 2001 and is issuing this replacement rule. These regulations provide additional protections for pregnant women and human fetuses involved in research. The final rule continues the special protections for pregnant women and human fetuses that have existed since 1975 and makes limited changes in terminology referring

to neonates, clarifies provisions for paternal consent when research is conducted involving fetuses, clarifies language that applies to research on newborns of uncertain viability, and corrects technical errors.

DATES: The final rule, Protection of Human Subjects, published in the **Federal Register** on January 17, 2001, at 66 FR 3878 is withdrawn as of November 13, 2001. The amendment published in this final rule is effective December 13, 2001.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections (OHRP) 200 Independence Avenue, S.W., Room 733–E, Washington, DC 20201. Telephone 202–260–1587.

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).

On January 17, 2001, the Department published in the **Federal Register** a Final Rule, with an effective date of March 19, 2001 (66 FR 3878), intended to amend subpart B of 45 CFR part 46. This preamble refers to that rule as ''the January rule.'' The January rule's effective date was delayed by 60 days on March 19, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled A Regulatory Review Plan, published in the **Federal Register** on January 24, 2001. (66 FR 15352). The effective date of the January rule was further delayed by 180 days on May 18, 2001 to give the Department an opportunity to obtain comment on three modifications to the rule. (66 FR 27559). Simultaneous with publication of this final rule, the January rule is being withdrawn. Given the imminence of the effective date of the final rule as amended, seeking public comment on the withdrawal of the January rule would have been impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of regulations, to allow time for implementation of this final rule.

On July 6, 2001, the Department published in the **Federal Register** a Notice of Proposed Rulemaking (66 FR 35576) seeking public comment on three limited proposed changes in the January rule: (1) Requiring paternal consent (with specified exceptions) for participation in federally funded research that is directed solely at a fetus; (2) modifying the definition of ''fetus'' to describe only the stage prior to delivery; and (3) modifying language to make clear that neonates of uncertain viability may be subjected to added risk only if the research is intended to enhance the probability of survival of the particular neonate to the point of viability.

Discussion of Comments

During the public comment period that ended September 4, 2001, the Department received 21 public comments on the proposed rule from interested parties. The comments are summarized as follows:

Paternal Consent for Participation in Research Directed Solely at the Fetus

The Department proposed requiring paternal consent (with specified exceptions) for participation in federally-funded research that is directed solely at the fetus. One commenter endorsed the change, saying that it is appropriate. Eight commenters objected to the change. Of these, two indicated that paternal consent should be required for any research that involves more than minimal risk to the fetus, and six indicated paternal consent should not be required in any research involving the fetus because to do so is contrary to clinical standards, does not recognize a woman's autonomy or her interest in protecting her fetus, presumes exclusion of pregnant women from participating in research, could delay participation in research, and could require pregnant women to disclose HIV status to fathers when such disclosure is not ordinarily required. These six commenters also stated that potential benefit to the mother and the fetus is not separable; and that determination of benefit is subjective.

The Department finds that modification of the consent provisions as proposed is the most respectful of the parents' joint interests in their fetus's health. The preamble to the January rule explained that consent requirements for research involving pregnant women were modified to address cases in which a requirement for the father's consent had been a barrier to participation in research which held potential benefit for both pregnant women and their fetuses. We believe that this problem is addressed by the clarification in this rule that only the mother's consent is required for participation in research that may benefit both the pregnant woman and the fetus. In addition, a father's consent would not be needed for a woman to participate in a research activity that would benefit her health.

Two commenters pointed out that consent requirements are not addressed for research with no prospect of benefit for the mother or her fetus, when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. The Department has modified the rule to clarify that only maternal consent is required in this circumstance, consistent with the other consent requirements of this section. The Department finds that requiring consent of both parents when risk to the fetus is no greater than minimal, and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, would potentially impede important research and would not create additional protections for the fetus.

Three commenters stated that the qualification that paternal consent need not be obtained if he is unable to consent because of ''unavailability, incompetence, or temporary incapacity'' is unclear, and questioned whether paternal consent is required in cases of rape. The Department has modified the rule to clarify that paternal consent is not required in cases of rape and incest.

Use of the Terms Fetus and Neonate

The Department proposed using the terms ''fetus'' to describe an infant prior to delivery, and ''neonate'' to describe an infant following delivery. Four commenters endorsed use of the term ''neonate'' to refer to an infant after delivery; one of these commenters added that the change is consistent with clinical definitions. Six commenters objected, stating that use of the term neonate is confusing, conflicts with traditional medical terminology, will cause research conducted under subpart B to overlap with research conducted under subpart D, and will cause mislabeling of fetal deaths.

The Department finds that using the term ''fetus'' only for those infants that

have not been delivered is preferable because it is more consistent with the ordinary understanding of that word and that it is appropriate to distinguish between infants that have and have not been delivered by introducing the term neonate for an infant that has been delivered. This definitional change does not alter the strong protections the rule gives to pregnant women and fetuses, or change the regulatory framework that has been established to guide decisions regarding conduct of federally-supported research. The Department recognizes that the term ''neonate'' customarily refers to the first 28 days of life following delivery. The rule is not intended to alter this customary definition. The rule categorizes research involving neonates of uncertain viability or nonviable neonates as covered by subpart B, and research involving viable neonates as covered by subpart D. The Department notes that subpart B applies only to research. Because the vast majority of fetuses and neonates are not involved in any research protocol, subpart B is not likely to alter the ways that fetal deaths generally are labeled and reported throughout the medical community.

Research Involving Neonates of Uncertain Viability

The Department proposed to clarify that research involving risk is permitted on neonates of uncertain viability only when it is intended to increase the probability of survival. One commenter supported this change. Four commenters objected, stating that the level of risk for neonates of uncertain viability should not be less than that for viable neonates, and that research involving these subjects should be covered under subpart D. Three of these commenters also stated that a ''no-risk'' standard for research is not feasible. The Department finds that it is appropriate to provide greater protections for neonates of uncertain viability and to make clear that these neonates may be subjected to added risk only if the research is intended to enhance the particular neonate's probability of survival to the point of viability. The Department has modified language concerning research that develops important biomedical knowledge that cannot be obtained by other means to clarify that such research can only be conducted on neonates of uncertain viability and nonviable neonates when it will pose no added risk. This language is consistent with statutory requirements under 42 U.S.C. 289g.

Further, three commenters proposed alternative definitions of viability, and one commented that determination of viability is not a one-time decision. The Department finds that the definition provided in the rule provides appropriate protection to neonates in this vulnerable status, and intends that the determination of viability be made at the time of enrollment in any relevant research.

General Comments

Six commenters stated that language from HHS appropriations statutes regarding research involving embryos should be incorporated into the regulations and that either a definition of ''embryo'' should be added to the regulations or the definition of ''fetus'' should be revised. One commenter noted that the definition of fetus contained in the regulations is confusing, as it includes embryos. And two commenters stated general opposition to any research involving embryos. The Department finds that the current definition of fetus contained in the regulations appropriately includes embryos in utero, and that research involving embryos is otherwise adequately addressed by existing statutory requirements.

Four commenters stated that the regulations should incorporate language from 42 U.S.C. 289g(b) regarding the risk standard for aborted fetuses and fetuses carried to term. The Department finds that existing regulations make no distinction between fetuses intended to be aborted and those to be carried to term and ensures that decisions regarding whether to carry the fetus to term are separate from the research. The Department also finds that these risk standards are appropriately addressed by existing statutes. These four commenters also stated that the regulations should retain the requirement that risk to the fetus should be no more than needed to meet the health needs of the mother or fetus. The Department believes that the existing standard, that the risk posed is the least possible for achieving objectives of research, more appropriately covers all research that may be conducted under this section. In some cases, the objective of the research is to potentially benefit the mother or her fetus. In other cases, the objective of the research is to develop important biomedical knowledge which cannot be obtained by any other means.

Four commenters stated that the regulations should incorporate statutes governing fetal tissue research. The Department finds that research involving fetal tissue is adequately addressed by existing statutory requirements, and that these requirements are referenced appropriately in section 46.206 of the rule. These four commenters, as well as two other commenters, noted that the provisions in the regulation concerning fetal tissue research inappropriately refer to the material as ''neonatal'' material. The Department has corrected this drafting error.

One commenter objected to the requirement that, where scientifically appropriate, preclinical studies on pregnant animals and clinical studies on non-pregnant women be conducted to provide data for assessing potential risks to pregnant women and fetuses because it may delay important research. The Department finds that such studies may provide important data regarding assessment of risks to pregnant women and fetuses.

One commenter observed that requirements regarding inducements and decisions to terminate a pregnancy are not relevant to research involving neonates. The Department has corrected this drafting error by deleting the previous 46.205(a)(3) and (4).

One commenter noted that the regulations do not directly address in vitro fertilization research, although this topic is listed in the title and a definition is provided. The Department has deleted in vitro fertilization research from the title and the definitions.

One commenter supported the Department's distinction between therapeutic and nontherapeutic research in this rule; and two commenters opposed making such a distinction. The Department has retained existing regulatory language, finding that such a distinction is a valid factor in assessing this type of proposed research.

Five commenters objected to the provision permitting the Secretary to conduct or fund research involving pregnant women, fetuses, or neonates that does not otherwise meet the requirements of the rule when the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of these subjects, will be conducted in accordance with sound ethical principles and with informed consent. The Department has retained this provision. While such research would not normally be supported, it is important to retain the flexibility to support such research to protect and advance the health and well-being of these subjects. This provision replaces a former requirement for review of such research by an ethics advisory board, which was nullified by 1993 legislation, Pub. L. 103–43. Moreover, the Secretary will, as required under the current section, consult with experts and seek public comment prior to determining

whether such research should be supported by the Department. Further, any such research must be conducted in accordance with sound ethical principles.

Two commenters objected to permitting use of exemptions found under subpart A of the regulations in research conducted under subpart B. The Department has retained this provision, finding that permitting these exemptions is consistent with other provisions of the rule, and will not increase risks to subjects covered by subpart B.

One commenter objected to the order of the definitions. The Department has retained alphabetical order for ease of reference.

One commenter noted that the change in presumption for inclusion in research, as modified in the January rule, creates an appearance of promoting research over protection of subjects. The Department has retained existing language, finding that it is important to promote a presumption of inclusion rather than exclusion, and to respect autonomy of research subjects.

One commenter questioned the deletion of the requirement for review by an Ethics Advisory Board in the January rule. As stated above, this change was made in light of 1993 legislation nullifying this requirement, Pub. L. 103–43.

One commenter questioned the delay of the effective date of the January rule, stating that the delay was implemented without public comment in a final rule published on May 16 (66 FR 27599). As stated in that notice of delay of effective date, the Department determined that notice and comment requirements of 5 U.S.C. 553 did not apply to that action because it was a rule of procedure, or, alternatively, because it fell within the good cause exception to rule making requirements because obtaining public comment was impracticable, unnecessary, and contrary to the public interest. See 5 U.S.C. 553(b)(3(B). Moreover, an opportunity for comment has been provided in connection with the issuance of these regulations.

Summary of Comments

After considering the comments, the Department is adopting the rule as proposed except for the changes noted above. Language is added to clarify that only maternal consent is required for research that does not involve any prospect of benefit for the mother or her fetus and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means and the risk to the fetus is not greater than minimal. Language is added to clarify that paternal consent is not required in cases of rape and incest. The term ''added'' is incorporated to clarify that research involving nonviable neonates and neonates of uncertain viability that may develop important biomedical knowledge that cannot be obtained by any other means may be conducted only when such research poses no added risk. Drafting errors, as noted above, are corrected.

The rule is effective December 13 2001. All initial and ongoing projects reviewed by Institutional Review Boards (IRBs) after the effective date under Assurances with DHHS, Office for Human Research Protections (OHRP) 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 Sec. 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: October 26, 2001.

Arthur J. Lawrence,

Acting Principal Deputy Assistant Secretary for Health.

Approved: October 29, 2001.

Tommy G. Thompson,

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:

PART 46—[AMENDED]

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. Subpart B of 45 CFR Part 46 is revised to read as follows:

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

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 neonates.
46.204 Research involving pregnant women or fetuses.
46.205 Research involving neonates.
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, fetuses, or neonates.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

§ 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, human fetuses, neonates of uncertain viability, or nonviable neonates 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 that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) 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.

(g) 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.

(h) Viable, as it pertains to the neonate, 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 neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

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

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.

Pregnant women or fetuses 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 caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

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

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

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

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

(i) 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

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

§ 46.205 Research involving neonates.

(a) Neonates of uncertain viability and nonviable neonates 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 neonates.

(2) Each individual 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 neonate.

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

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

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate 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 neonate to the point of viability, and any risk is the least possible for achieving that objective, 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 added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate 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, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

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

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

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

(3) There will be no added risk to the neonate 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 neonate 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 neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable 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, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 or § 46.205 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, fetuses or neonates; 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, fetuses or neonates;

(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.

[FR Doc. 01–28440 Filed 11–9–01; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AH79

Migratory Bird Hunting; Late Seasons and Bag and Possession Limits for Certain Migratory Game Birds; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: The U.S. Fish and Wildlife Service (hereinafter Service or we) published a document in the September 28, 2001, **Federal Register** prescribing the hunting seasons, hours, areas, and daily bag and possession limits for general waterfowl seasons and those early seasons for which States previously deferred selection. This document corrects errors in the season dates and other pertinent information for the States of Illinois, North Carolina, South Carolina, Texas, and Vermont.

DATES: This rule was effective on September 28, 2001.

FOR FURTHER INFORMATION CONTACT: Jon Andrew, Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, (703) 358–1714.

SUPPLEMENTARY INFORMATION: In the September 28, 2001, **Federal Register** (66 FR 49748), we published a final rule prescribing hunting seasons, hours, areas, and daily bag and possession limits for general waterfowl seasons, certain other migratory bird seasons, and those early seasons for which States previously deferred selection. The rule contained errors in the entries for Illinois, North Carolina, South Carolina, Texas, and Vermont, which are discussed briefly below and corrected by this notice.

We received public comment on the proposed rules for the seasons and limits established by the September 28 final rule. We addressed these comments in final rules published in the August 21, 2001, (66 FR 44010) and September 27, 2001, (66 FR 49478) **Federal Registers**. The corrections are typographical in nature and involve no substantial changes to the substance in the contents of the prior proposed and final rules.

In rule FR Doc. 01–24292 published September 28, 2001 (66 FR 49748), make the following corrections:

§ 20.105 [Corrected]

1. On page 49756 under the heading Vermont, subheading Canada Geese, the subheadings ''Lake Champlain and Interior Zones'' and ''Connecticut River Zone'' are inserted; across from the subheading Lake Champlain and Interior Zones, the season dates of ''Oct. 27–Nov. 25'' are inserted; across from the subheading Connecticut River Zone, the season dates of ''Oct. 2–Nov. 4 & Nov. 21–Dec. 1'' are inserted.

2. On page 49756 under the heading Vermont, subheading Light Geese, the subheadings ''Lake Champlain and Interior Zones'' and ''Connecticut River Zone'' are inserted; across from the subheading Lake Champlain and Interior Zones, the season dates of ''Oct. 10–Dec. 28 & Mar. 1–Mar. 10'' are inserted; across from the subheading Connecticut River Zone, the season dates of ''Oct. 2–Dec. 16'' are inserted.

3. On page 49756 under the heading West Virginia, subheading Canada Geese, subheading Zone 2, the season dates of ''Dec. 21 Jan. 31'' are corrected to read ''Dec. 21–Jan.31.''

4. On page 49757 under the heading Illinois, subheading Brant, the bag and possession limits are corrected to read ''1 and 2.'' Remove the ''2'' from under the subheading Brant.

5. On page 49762 under the heading Texas, subheading Geese, subheading East Tier, subheading Light Geese, the season dates ''Oct.28–Jan.21'' are corrected to read ''Oct. 27–Jan. 20.''

6. On page 49766 under the heading North Carolina, the season dates for the youth waterfowl hunting day are