40 FR 154, **Aug 8, 1975** Final Rule on Amendements to Protection of Human Subjects Approved by Caspar W. Weinberger, Secretary of HEW	40 FR 215 **November 6, 1975**, limited amendment (thus no proposed rule) final rule. Approved by David Matthews, Secretary.	42 FR 2792 January 13, 1977 Proposed Rule	43 FR 1758 **January 11, 1978** final rule. Approved by Joseph Califano, Jr., Secretary
	[changes enlarged and bolded]		[changes enlarged and bolded]
[Adding the following <u>new</u> Subparts B and C to Part 46 of 45 CFR]			
Subpart B--Additional Protections Pertaining to Research, Development, and Related Activites Involving Fetuses, Pregnant Women, and Human *In Vitro* Fertilization			
§ 46.201 Applicability. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.			
(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinant State or local laws bearing upon the activities covered by this subpart.			

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.			
§ 46.202 Purpose. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.			
§ 46.203 Definitions. As used in this subpart: (a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Edcuation, and Welfare to whom authority has been delegated.			
(b) "Pregnancy" encompasses the period of time from confirmaiton of implantation until expulsion or extraction of the fetus.			(b) "Pregnancy" encompasses the period of time from confirmation of implantation **(through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test),** until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation until a determination is made, following expulsion or extraction of the fetus, that it is viable.			(c) "Fetus" means the product of conception from the time of implantation **(as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test),** until a determination is made, following expulsion or extraction of the fetus, that it is viable.
(d) "Viable" as it pertains to the fetus means being able, after either spontaneious or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat 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 is viable after delivery, it is a permature infant.			
(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.			
(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeart, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).			

(g) "*In vitro* fertilization" means any fertilization of human ova which occures outside the body of a female, either through admixture of donor human sperm and ova or by any other means.			
§ 46.204 Ethical Advisory Boards. (a) Two Ethcial Advisory Boards shall be established by the Secretary. Members of these Boards shall be so selcted that the Boards will be competent to deal with medical, legal, social, ethcial, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representaitves of the general public. No board member may be a regular, full-time employee of the Federal Government.			**§ 46.204 Ethical Advisory Boards** (a) ~~Two~~ **One or more** Ethcial Advisory Boards shall be established by the Secretary. Members of these Board**(s)** shall be so selcted that the Board**(s)** will be competent to deal with medical, legal, social, ethcial, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Federal Government **Department of Health, Education, and Welfare**.

(b) One Board shall be advisory to the Public Health Service and its components. One Board shall be advisory to all other agencies and componnets with the Department of Health, Education and Welfare.			~~(b) One Board shall be advisory to the Public Health Service and its components. One Board shall be advisory to all other agencies and components with the Department of Health, Education and Welfare.~~
(c) At the request of the Secretary, the appropraite Ethical Advisory Board shall render advice consistent with policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the appropriate Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.			~~(c)~~ **(b)** At the request of the Secretary, the ~~appropriate~~ Ethical Advisory Board shall render advice consistent with policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the ~~appropriate~~ Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.
(d) A Board may establish, with the appoval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.			~~(d)~~ **(c)** A Board may establish, with the appoval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(e) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.			~~(e)~~ **(d)** No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human *in vitro* fertilization.			
(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offerer's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:			

(1) Determine that all aspects of the activity meet the requirements of this subpart;			
(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected and adequate provision has been made by the applicant or offerer for monitoring the actual informed consent process (e.g. through such mechanisims, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);			
(3) Carry out such other responsibilities as may be assigned by the Secretary.			
(b) No award may be issued until the applicant or offerer has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.115 of Subpart A of this part.			
(c) Applicants or offerers seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.			

§ 46.206 General Limitations (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 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.	**§ 46.206 General Limitations** (a) …(2) Except where the purpose of the activity is to meet the health needs of the **mother or** 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;		
(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.			

§ 46.207 Activities directed toward pregnant women as subjects. (a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother 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 is minimal.			
(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 after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; (4) the pregnancy resulted from rape.			

§ 46.208 Activities directed toward fetuses *in utero* as subjects. (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**.**			
§ 46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects. (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.			**§ 46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.** (a) ~~No fetus *ex utero* may be involved as a subject in an activity covered by this subpart u~~**U**ntil it has been ascertained whether **or not** ~~the particular~~ **a** fetus **ex utero** is viable, **a fetus ex utero may not be involved as a subject in an activity covered by this subpart** unless: (1) 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 **or (2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.**

(b) No nonviable fetus may be involved as a 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.			(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 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.			

(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.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from the dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offerer (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

43 FR 31786 July 21 1978 Research Involving Children, proposed rule	~~44 FR 47688~~ August 14, 1979 Proposed Regulations Amendment Basic HEW Policy for Protection of Human Research ~~Subjects~~	46FR 8366 January 26, 1981 final rule. Approved by Patricia Harris, Secretary.	48 FR 9814 March 8, 1983 final rule. Approved by Richard Schweiker, Secretary	56 FR 28032 June 18, 1991 technical amendment regarding subpart D children subjects
		[changes enlarged and bolded]		
		[Scraps entire Subpart A and replaces it with stuff about IRBs & Scraps entire Subpart D.]	[Re-instates Subpart D]	
				Subpart B -- Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human *In Vitro* Fertilization
				§46.201 Applicability. (a) The regulations in this subpart are applicable to all ~~Department of Health, Education, and Welfare~~ **Department of Health and Human Services** grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.
				(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

				(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.
				§ 46.202 Purpose. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.
				§46.203 Definitions. As used in this subpart:(a) "Secretary" means the ~~Secretary of Health, Education, and Welfare~~ **Secretary of Health and Human Services** and any other officer or employee of the ~~Department of Health, Edcuation, and Welfare~~ **Department of Health and Human Services (DHHS)** to whom authority has been delegated.
				(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

				(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.
				(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat 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 is viable after delivery, it is a premature infant.
				(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.
				(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

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

				(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.
				(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

				(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

				§46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human *in vitro* fertilization.
				(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

				(1) determine that all aspects of the activity meet the requirements of this subpart;
				(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);
				(3) carry out such other responsibilities as may be assigned by the Secretary.
		(b) No award may be issued until the applicant or offerer has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in ~~§ 46.115~~ **§ 46.120** of Subpart A of this part.		(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in §46.120 of Subpart A of this part.
				(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

				§46.206 General limitations. (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 mother or 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 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.

				§ 46.207 Activities directed toward pregnant women as subjects. (a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother 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 is minimal.
				(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 after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; **or** (4) the pregnancy resulted from rape.

				§ 46.208 Activities directed toward fetuses *in utero* as subjects. (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 ofthe 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.
				§46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects. (a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or (2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

				(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:(1) vital functions of the fetus will not be artificially maintained, (2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and (3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
				(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.
				(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.
				§ 46.210 Activities involving the dead fetus, fetal material, or the placenta. Activities involving the dead fetus, mascerated 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.

				§46.211 Modification or waiver of specific requirements. Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the **sum of** the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register.

56 FR June 28, 1991 Correction left of a number in section heading	59 FR 28276 June 1, 1994 final rule. Approved by Donna Shalala, Secretary	May 20 1998 proposed rule. Donna Shalala	January 17, 2001 66 FR 3878 Final Rule	
	Subpart B--Additional ~~DHHS~~ Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human *In Vitro* Fertilization	**Subpart B-- Additional DHHS Protections for Pregnant Women, Human Fetuses, and Newborns Involved as Subjects in Research, and Pertaining to Human In Vitro Fertilization.**	**Subpart B--Additional Protections ~~Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization.~~ for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization.**	
	§ 46.201 Applicability. (a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human in vitro fertilization.	**~~§ 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 newborns as subjects, 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 Department	**§ 46.201 ~~Applicability.~~ 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) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.	(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.	(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.	

	(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.	(c) The additions, exceptions, and provisions for waiver as they appear in 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	(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.	(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.	
	§ 46.202 Purpose. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.		~~**§ 46.202 Purpose.**~~ ~~It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.~~	
	§ 46.203 Definitions. As used in this subpart: (a) 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.	**§ 46.202 Definitions.** The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart: (a) (f) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.	~~**§ 46.203**~~ **§ 46.202 Definitions.** The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart: ~~(f)~~ (a) Dead fetus means a fetus ~~ex utero which~~ after delivery that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord ~~(if still attached)~~. ~~Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means~~.	
	(b) Pregnancy encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.	(b) (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.	~~(c)~~ (b) Fetus means the product of conception from ~~the time of~~ implantation ~~(through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test),~~ until a determination is made~~, following expulsion or extraction of the fetus,~~ after delivery that it is viable.	

	(c) Fetus means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.	(c) (b) Fetus means the product of conception during pregnancy until a determination is made after delivery that it is viable.	~~(g)~~ (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.	
		delivery.		
	(d) Viable as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat 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 is viable after delivery, it is a premature infant.	(e) (d) Nonviable fetus or nonviable newborn means a newborn or fetus after delivery that, although living, is not viable.	~~(e)~~ (d) Nonviable fetus means a fetus ~~*ex utero*~~ after delivery that, although living, is not viable.	
	(e) Nonviable fetus means a fetus ex utero which, although living, is not viable.	(f) (a) Dead fetus or dead newborn means a newborn or fetus after delivery which that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached). Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.	~~(b)~~ (e) Pregnancy encompasses the period of time from ~~confirmation of~~ implantation ~~(through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.~~ 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) Dead fetus means a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).	(g) Viable ~~as it pertains to the~~ fetus or viable newborn means a newborn that is able 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 or newborn is viable for purposes of this subpart. If a newborn fetus after	~~(a)~~ (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) *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)~~ (g) Viable as it pertains to the fetus means being able, after ~~either spontaneous or induced~~ 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 is viable after delivery, it is a premature infant.~~ 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.	
			1994 § 46.204 on Ethical Advisory Boards is struck in the 2001 Clinton Regs	
	§ 46.204 Ethical Advisory Boards. (a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Bboard(s) shall be so selected that the Bboard(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health and Human Services.	**§ 46.203 Duties of IRBs in connection with research involving pregnant women, human fetuses, newborns, 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.	The changes in Sections 46.203 through 46.207 in the 2001 document can be found on attatched document.	

		§ 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	**§ 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. SEE 1994 SECTION 46.205; THIS IS A REPLACEMENT OF THAT SECTION WITH SIGNIFICIANT ALTERATION OF IRB DUTIES.	
	(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.	(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 activities designed to meet the health needs of the mother or her fetus; interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;	**§ 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;	
	(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.	c) Any risk is the least possible for achieving the objectives of the research.	(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;	

	~~*(d) No application or proposal involving human in vitro fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.*~~ [Nullified under Public Law 103-43, June 10, 1993]	(d) The woman is fully informed regarding the reasonably foreseeable impact of the research on the fetus (or a resultant child);	(c) Any risk is the least possible for achieving the objectives of the research;	
		(e) (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;	(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);	
		(f) For pregnant 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;	(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;	
		(g) (h) Individuals engaged in the research will have no part in: (1) Aany decisions as to the timing, method, or procedures used to abort terminate a pregnancy, or (2) Determining the viability of a newborn; and MOVED (2) DOWN 2 ROWS WITH FURTHER ALTERATIONS	(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;	

		(h) (g) No inducements, monetary or otherwise, will be offered to abort terminate a pregnancy.		
			(g) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	
		(i) Individuals engaged in the research will have no part in... determining the viability of a newborn fetus.	(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	
	§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.	**Sec. 46.205 Research involving newborns of uncertain viability, nonviable newborns, and viable newborns fetuses after delivery.**	(i) Individuals engaged in the research will have no part in determining the viability of a fetus.	
	(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part,the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:	(a) After delivery, fetuses may be involved in research if all of the following conditions are met:	**§ 46.205 Research involving fetuses after delivery.**	

	(1) Determine that all aspects of the activity meet the requirements of this subpart;	(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.	(a) After delivery, fetuses may be involved in research if all of the following conditions are met:	
	(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);	(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.	(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.	
	(3) Carry out such other responsibilities as may be assigned by the Secretary	(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.	(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.	
	(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in Sec. 46.120 of Subpart A of this part.	(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.	(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.	
	(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.	(5) Individuals engaged in the research will have no part in determining the viability of a fetus.	(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.	

		(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.	(5) Individuals engaged in the research will have no part in determining the viability of a fetus.	
		(a) (b) Newborns of uncertain viability. After delivery, and until it has been ascertained whether or not a newborn viable is viable, a newborn fetus may not be involved as a subject in research covered by this subpart unless both of the conditions in paragraphs (a)(1) and (2) of this section the following additional conditions are met:	(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.	
		(1) The purpose of the research is IRB determines that: (i) The research holds out the prospect of enhancing To enhance the possibility the probability of survival of the particular newborn 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 Tthe development of important biomedical knowledge	(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:	
		(2) The legally effective informed consent of the mother or the father either parent of the newborn fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of the mother's or the father's either parent's legally authorized representative is obtained in accord with Subpart A of this part., unless altered or waived in	(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	

		(b) (c) Nonviable newborns fetuses. After delivery, a nonviable newborn fetus may not be involved as a subject in research covered by this subpart unless all of the following conditions are met:	(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).	
		(1) Vital functions of the newborn fetus will not be artificially maintained;	(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:	
		(2) The research will not terminate the heartbeat or respiration of the newborn fetus;	(1) Vital functions of the fetus will not be artificially maintained;	
		(3) There will be no added risk to the fetus of suffering injury or death resulting from the research; and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and MOVED	(2) The research will not terminate the heartbeat or respiration of the fetus;	
		(4) tThe purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	(3) There will be no risk to the fetus resulting from the research;	
		(4) (5) The legally effective informed consents of both the mother and the father parents of the newborn fetus are obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 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 the other one parent of a nonviable newborn fetus will suffice to meet the informed consent requirement of	(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	

		(c) (d) Viable newborns fetuses. A viable newborn fetus, after delivery, that has been determined to be viable is a child as defined by Sec. 46.402(a) and may be included as a subject in research only to the extent permitted by and in accord with the requirements of Subparts A and D	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.	
	§ 46.206 General limitations. (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 mother or 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 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.	**Sec. 46.206 Research involving, after delivery, the placenta, the dead newborn fetus, or fetal material.** (a) Research involving, after delivery, the placenta; the dead newborn fetus; macerated fetal material; or cells, tissue, or organs excised from a dead newborn fetus shall be conducted only in accord with any applicable Federal, State or local laws and regulations regarding such activities.	(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.	
	(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.	(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living persons can be identified, directly or through identifiers linked to those persons individuals, those persons individuals are research	**§ 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.	

	§ 46.207 Activities directed toward pregnant women as subjects. (a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother 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 is minimal.	**Sec. 46.207 Modification or waiver of specific requirements. 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	(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.	
	(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 after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.	(b) The Secretary may modify or waive specific requirements of this subpart for specific research projects or classes of research, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and after following opportunity for public review and comment, including a public meeting announced in the Federal Register, as 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	**§ 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	

	§ 46.208 Activities directed toward fetuses in utero as subjects. (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) 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).	
	(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.			
	§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects. (a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless: (1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or (2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.			

	(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless: (1) Vital functions of the fetus will not be artificially maintained, (2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and (3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.			
	(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.			
	(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.			
	§ 46.210 Activities involving the dead fetus, fetal material, or the placenta. Activities involving the dead fetus, mascerated 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.			

	§ 46.211 Modification or waiver of specific requirements. Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register.			

2001 § 46.203	1994 § 46.205		2001 § 46.204	1994 §§ 46.206, 207, 208		2001 §46.205	1994 § 46.209	
Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization.	**Additional duties of the Institutional Review Boards in connection with activities research involving fetuses, pregnant women, or human in vitro fertilization.** [Fetuses and Pregnant Women are not in order]		**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;	**46.206 General limitations.** (a) No activity to which this subpart is applicable may be undertaken unless: Pregnant women or fetuses prior to delivery may be involved in researh only if all of the following conditions are met: (1) (a) Where scientifically Aappropriate, preclinical studies on animals and nonpregnant individuals have been completed including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and proved data for assessing potential risks to pregnant women and fetuses;		**Research involving fetuses after delivery.**	**Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects. Research involvong fetuses after delivery.** (a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless: After delivery, fetuses may be involved in research if all of the following conditions are met:	

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.	(a) In addition to the other responsibilities prescribed for assigned to Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board each IRB shall review research, with respect to activities covered by this subpart, carry out the following additional duties: and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.		(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;	(2) (b) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is not greater than minimal and, in all cases, is the least possible risk for achieving the objectives of the activity. 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;		(a) After delivery, fetuses may be involved in research if all of the following conditions are met:	(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or (2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.	

	(1) Determine that all aspects of the activity meet the requirements of this subpart; [This resembles the final clause of the 2001 document]		(c) Any risk is the least possible for achieving the objectives of the research;	(3) (h) Individuals engaged in the activity research will have no part in: (i) Aany decisions as to the timing, method, and or procedures used to terminate the a pregnancy,; and (ii) (i) [From 2001] Individuals engaged in the research will have no part in determining the viability of the a fetus at the termination of the pregnancy; and (4) No procedural changes which may cause greater than minimal 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.		(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.	(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.	

	(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);		(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);	(g) (b) No inducements, monetary or otherwise, may will be offered to terminate a pregnancy for purposes of the activity.		(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.	(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) Carry out such other responsibilities as may be assigned by the Secretary		(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;	**46.207 Activities directed toward pregnant women as subjects.** (a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother 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 is minimal.		(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.	(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.	

	(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in Sec. 46.120 of Subpart A of this part.		(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;	(b) (d) & (e) 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 after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape. (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;		(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.	(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.	

	(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.			**46.208 Activities directed toward fetuses in utero as subjects.** (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.		(5) Individuals engaged in the research will have no part in determining the viability of a fetus.	(5) Individuals engaged in the research will have no part in determining the viability of a fetus.	

			(g) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	(b) (d) & (e) 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. (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;		(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.	(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.	
			(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			(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:	(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:	

			(i) Individuals engaged in the research will have no part in determining the viability of a fetus.			(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	(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	
				(c) Any risk is the least possible for achieving the objectives of the research;		(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).	(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).	
				(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;			(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.	

						(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:	(b) (c) No nNonviable fetuses. After delivery, a nonviable fetus may not be involved in research as a subject in an activity covered by this subpart unless all the following conditions are met: (1) Vital functions of the fetus will not be artificially maintained, (2) Experimental activities which of themselves would The research will not terminate the heartbeat or respiration of the fetus will not be employed, and; (3) There will be no risk to the fetus resulting from the research;	
						(1) Vital functions of the fetus will not be artificially maintained;	(1) Vital functions of the fetus will not be artificially maintained,	
						(2) The research will not terminate the heartbeat or respiration of the fetus;	(2) Experimental activities which of themselves would The research will not terminate the heartbeat or respiration of the fetus will not be employed, and;	
						(3) There will be no risk to the fetus resulting from the research;	(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	(3) (4) The purpose of the activity research is the development of important biomedical knowledge which cannot be obtained by other means;	

						(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.	(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.	(c) (d) Viable fetuses. In the event the fetus ex utero is found to be viable, A fetus, after delivery, that has been determined to be viable is a child as defined by Sec. 46.402(a) and it may be included as a subject in the activity in research only to the extent permitted by and in accordance with the requirements of other subparts A and D of this part.	
							(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.	

2001 § 46.206	1994 § 46.210		2001 § 46.207	1994 § 46.211										
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.	**Activities Research involving, after delivery, the placenta, the dead fetus, or fetal material, or the placenta.** Activities Research involving, after delivery, the placenta; involving the dead fetus,; mascerated fetal material,; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accordance with any applicable Federal, State or local laws and regulations regarding such activities.		**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.**	**Modification or waiver of specific requirements. 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.**									

(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.	(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.		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	Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register. 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).	(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).