Preg45CFR 46 Subpart B
Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

For all research involving pregnant[6] women, human fetuses,[3] neonates[4] of uncertain viability,[8] or nonviable neonates.[5]
As required by OHRP the final decision of the risk category will be established at the IRB meeting and reflected in the letters and minutes.

45CFR46	***Category***	***Explanation***
46.204	**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; 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, 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 Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of the Protections for Children Involved as Subjects (Subpart D); 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.

AAHRPP Elements: II.4.A-B

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 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 45CFR46.204 (above) have been met as applicable.
46.205	**Research involving neonates** 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*** have been 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, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
46.205	**Research involving neonates** 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, except that the waiver and alteration provisions of 45CFR 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, 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.
46.205	**Research involving neonates** (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 the Federal Policy for Protection of Human Subjects and Protections for Children Involved as Subjects (Subpart D).

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[7] will conduct or fund research that the IRB does not believe meets the requirements of Sec. 46.204 or Sec. 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 Sec. 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 Federal Policy for Protection of Human Subjects (Subpart A).

[1] "*Dead fetus* means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord," 45CFR46.202

[2] "*Delivery* means complete separation of the fetus from the woman by expulsion or extraction or any other means," 45CFR46.202

[3] "*Fetus* means the product of conception from implantation until delivery," 45CFR46.202

[4] "*Neonate* means a newborn," 45CFR46.202

[5] "*Nonviable neonate* means a neonate after delivery that, although living, is not viable," 45CFR46.202

[6] "*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," 45CFR46.202

[7] "*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," 45CFR46.202

[8] "*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," 45CFR46.202

[9] "*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," 45CFR46.102