Research After Delivery

§ 46.205 (a) After delivery, fetuses may be involved in research if all of the following conditions are met: (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses. (2) The individual(s) providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child. (3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy. (4) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. (5) Individuals engaged in the research will have no part in determining the viability of a fetus. (6) The requirements of paragraph (b) or (c) of this section have been met as applicable.

—Clinton Administration's HHS Final Rule, 45 CFR Part 46, Protection of Human Research Subjects, January 17, 2001

Uncertain Viability

(b) Fetuses of uncertain viability. After delivery, and until it has been ascertained whether or not a fetus is viable, a fetus may not be involved in research covered by this subpart unless the following additional conditions are met: (1) The IRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research, or (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research; and (2) The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d).

Nonviable

(c) Nonviable fetuses. After delivery, a nonviable fetus may not be involved in research covered by this subpart unless all of the following additional conditions are met: (1) Vital functions of the fetus will not be artificially maintained; (2) The research will not terminate the heartbeat or respiration of the fetus; (3) There will be no risk to the fetus resulting from the research; (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and(5) The legally effective informed consent of both parents of the fetus is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.

Viable

(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.

RSC
Republican Study Committee