

Vulnerable Populations

Subpart B

Requirement for IRB to make Protocol Specific
Determinations

AAHRRP Element II.4.A

The IRB has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.

HRPP 8.4

Research Involving Pregnant Women, Fetuses, and Neonates

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;

HRPP 8.4

Research Involving Pregnant Women, Fetuses, and Neonates (cont.)

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

HRPP 8.4

Research Involving Pregnant Women, Fetuses, and Neonates

- (e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A, 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;

HRPP 8.4

Research Involving Pregnant Women, Fetuses, and Neonates (Cont.)

- (g) For children who are pregnant, assent and permission are obtained in accord with the provisions of 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.

Neonates

- (a) Neonates of uncertain viability and nonviable neonates may be involved in research if *all* of the following conditions are met:
- (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
 - (2) Each individual providing consent under paragraph [\(b\)\(2\)](#) or [\(c\)\(5\)](#) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate

Neonates (Cont.)

- (3) Individuals engaged in the research will have no part in determining the viability of a neonate.
- (4) The requirements of paragraph (b) or (c) of this section have been met as applicable.
- (b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

Neonates (Cont.)

(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

Neonates (Cont.)

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Neonates (Cont.)

- (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;

Neonates (Cont.)

- 4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- (5) The legally effective informed consent of both parents of the neonate is obtained in accord with [subpart A](#), except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

IRB Determinations and Documentation

- Determine that all requirements of Subpart B are met and document determination in the IRB minutes. This includes the determination regarding the requirements surrounding informed consent of the both the mother and father.

Questions?

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