1 PURPOSE

1.1. The purpose of this guidance is to describe the processes for conducting non-exempt research with pregnant women, fetuses, and neonates.

2 BACKGROUND

2.1. “Fetus” means:

2.1.1. the product of conception from implantation until delivery.

2.2. “Neonate” means:

2.2.1. a newborn.

2.3. “Nonviable neonate” means:

2.3.1. A neonate after delivery that, although living, is not viable.

2.4. “Pregnancy”

2.4.1. 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.

2.5. “Viable” means:

2.5.1. Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

2.6. The guidance provided is reflective of Federal regulations, Title 45, part 46, Subpart B. The state of Florida may have additional regulations when conducting research with this population. It is the responsibility of the researcher to ensure that all state and local laws are followed.

3 GUIDANCE

3.1. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

3.1.1. 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.

3.1.2. 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.

3.1.3. Any risk is the least possible for achieving the objectives of the research.

3.1.4. 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.

3.1.5. 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.

3.1.6. The pregnant woman and the father, if applicable, are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
3.1.7. For children who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D of the DHHS regulations.
3.1.8. No Inducements, monetary or otherwise, will be offered to terminate a pregnancy.
3.1.9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
3.1.10. Individuals engaged in the research will have no part in determining the viability of a neonate.

3.2. 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 research involving children. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

3.2.1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
3.2.2. Each Individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3.2.3. Individuals engaged in the research will have no part in determining the viability of a neonate.
3.2.4. The additional requirements for research involving neonates of uncertain viability or non-viable neonates (see below) have been met as applicable.

3.2.4.1. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met. An IRB must determine:

3.2.4.1.1. 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*;
3.2.4.1.2. 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**
3.2.4.1.3. The legally effective 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 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.

3.2.4.2. After delivery, nonviable neonates may not be involved in research unless all of the following additional conditions are met:

3.2.4.2.1. Vital functions of the neonate will not be artificially maintained;
3.2.4.2.2. The research will not terminate the heartbeat or respiration of the neonate;
3.2.4.2.3. There will be no added risk to the neonate resulting from the research;
3.2.4.2.4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; **and**

3.2.4.2.5. The legally effective consent of both parents of the neonate is obtained in accordance with Subpart A 45CFR46, except that the waiver and alteration provisions for consent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the 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 to meet the requirements of this paragraph.

3.3. 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.

4 REFERENCES

4.1. 45 CFR 46 Subpart B
4.2. 45 CFR 46 Subpart D
4.3. 21 CFR 50 Subpart B
4.4. 21 CFR 50 Subpart D