REGULATORY GUIDANCE: Pregnant Women and Fetuses

All criteria in 1, 2, or 3 must be met

1. Research involving pregnant women as subjects that involves no more than <Minimal Risk> to subjects and is not subject to regulation

1.1 The research presents no more than <Minimal Risk> to subjects (see Footnote 1)
1.2 The research is not subject to DHS, EPA, HHS, or VA regulation

2. Research involving pregnant women or fetuses that involves greater than <Minimal Risk> or is subject to regulation

2.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-<Pregnant Women>, have been conducted and provide data for assessing potential risks to <Pregnant Women> and <Fetuses>

2.2

- 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>
- The risk to the <Fetus> is not greater than Minimal Risk

2.2.1

- The research is not subject to DHS, EPA, or VA regulation and is not HHS-supported
- The purpose of the research is the development of important knowledge which cannot be obtained by any other means

2.3 Any risk is the least possible for achieving the objectives of the research

2.4 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the <Fetus> or neonate

2.5 No inducements, monetary or otherwise, will be offered to terminate a pregnancy

2.6 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy

2.7 Individuals engaged in the research will have no part in determining the viability of a neonate

2.8 For children who are pregnant, assent and permission are obtained in accordance with the regulations.

2.9

- The research is greater than minimal risk, but holds out the prospect of direct benefit to the pregnant woman or both the pregnant woman and the fetus

The mother's consent is obtained in accordance and documented in accordance with Sections 2 and 3 of "REGULATORY GUIDANCE: Criteria for Approval (HRP-400)"

- The research is greater than minimal risk, but holds out the prospect of direct benefit to solely to the fetus

The consent of the pregnant woman and the father is obtained and documented in accordance with Sections 2 and 3 of "REGULATORY GUIDANCE: Criteria for Approval (HRP-400)", 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.

2.10 When research involves pregnant women, the IRB determines that the consent of the pregnant women is required if the research holds out no prospect of benefit for the woman or 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.

3. Research involving pregnant women or fetuses that is not otherwise approvable

3.1 The research does not meet the above requirements

3.2 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

3.3 An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) 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, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required. (see Footnote 2)
4. Footnote

4.1 Research involving a live fetus or premature infant prior to or subsequent to any termination of pregnancy is only permitted under Florida Law if the procedure is necessary to protect or preserve the life and health of the fetus or premature infant. Seek advice from General Counsel.

4.2 DOD requires application of HHS Subpart B to research involving <Pregnant Women> and <Fetuses> that is more than <Minimal Risk> and includes interventions or invasive procedures to the woman or the <Fetus>, and to research involving <Fetuses> or neonates as participants. This organization elects to apply HHS Subpart B to all research involving <Pregnant Women> and <Fetuses> and involving greater than <Minimal Risk>, regardless of funding.

4.3 For DOD research, for federal research, the meeting is announced in the Federal Register. For all other research, the official is the <Institutional Official>.