This guidance document is used to determine and document whether non-exempt <Human Research> involving <Pregnant Women> can be approved.

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 45 CFR §46.204
   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 One of the following is true:
      2.2.1 One of the following is true:
         ○ The research is not subject to DHS, EPA, or VA regulation and is not HHS-supported
         ○ The research presents no more than <Minimal Risk> to the Fetus
         ○ The research is not subject to DHS, EPA, or VA regulation and is not HHS-supported
         ○ The research presents no more than <Minimal Risk> to the Fetus
   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 One of the following is true:
      ○ 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 research is greater than minimal risk, but holds out the prospect of direct benefit to solely to the fetus
      ○ The research is greater than minimal risk, but holds out the prospect of direct benefit to the woman or the Fetus
      ○ The research is greater than minimal risk, but holds out the prospect of direct benefit to the woman or the Fetus

3. Research involving pregnant women or fetuses that is not otherwise approvable 45 CFR §46.207
   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>.