**Pregnant Women and Fetuses:**

1. **Is the intervention or interaction solely of a behavioral nature (i.e. involving no medical intervention and no strenuous physical activity) presenting no known risks to the fetus or newborn child? (If “Yes” then no further determinations are necessary for the inclusion of pregnant women in research).**
   - Yes / No

2. **Have there been sufficient preclinical studies conducted for assessing potential risks to pregnant women and fetuses? (If “No” then pregnant women and fetuses may not be included in this research).**
   - Yes / No

3. **Is any risk the least possible for achieving the objectives of the research? (If “No” then pregnant women and fetuses may not be included in this research).**
   - Yes / No

4. **Are there inducements, monetary or otherwise, offered to terminate a pregnancy? (If “Yes” then pregnant women and fetuses may not be included in this research).**
   - Yes / No

5. **Do the individuals engaged in the research have any part in decisions regarding termination of a pregnancy or determining the viability of a neonate (If “Yes” then pregnant women and fetuses may not be included in this research).**
   - Yes / No

6. **Indicate all that apply (If neither, then pregnant women and fetuses may not be included in this research):**
   - Any 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 and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
   - 1 / 2 / Neither

7. **Indicate all that apply (If none, then pregnant women and fetuses may not be included in this research):**
   - Direct benefit solely to the fetus. Consent of both the pregnant woman and the father are obtained. Consenters are fully informed about the impact of the research on the fetus or neonate.
   - Direct benefits to the pregnant woman and/or the fetus. Consent of the pregnant woman is obtained who is fully informed about the impact of the research on the fetus or neonate.
   - No prospect of benefit for the woman or the fetus. Risk to the fetus is not greater than minimal. Purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means. Consent of the pregnant woman is obtained who is fully informed about the impact of the research on the fetus or neonate.
   - 1 / 2 / 3 / None

8. **Does the research meet assent and parental permission requirements for the inclusion of pregnant minors in the study? (If “No” then pregnant minors may not be included in this research).**
   - Yes / No

If the research does not meet the above requirements for the inclusion of pregnant women and fetuses then the research may involve pregnant women and fetuses by qualifying as “research not otherwise approvable” below.

**Neonates of Uncertain Viability:**

1. **Have there been sufficient preclinical studies conducted for assessing potential risks to neonates? (If “No” then neonates of uncertain viability may not be included in this research).**
   - Yes / No

2. **Do the individuals engaged in the research have any part in determining the viability of a neonate? (If “Yes” then neonates of uncertain viability may not be included in this research).**
   - Yes / No

3. **Indicate all that apply (If none, then neonates of uncertain viability may not be included in this research):**
   - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, with the least possible risk.
   - 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.
   - 1 / 2 / None

4. **Does the informed consent process meet the requirements for inclusion of neonates of uncertain viability (refer to guidelines for specific requirements)? (If “No” then neonates of uncertain viability may not be included in this research).**
   - Yes / No

If the research does not meet the above requirements for the inclusion of neonates of uncertain viability then the research may involve this population only by qualifying as “research not otherwise approvable” below.
Nonviable Neonates:

1. Have there been sufficient preclinical studies conducted for assessing potential risks to neonates? (If “No” then nonviable neonates may not be included in this research). Yes / No

2. Do the individuals engaged in the research have a part in determining the viability of a neonate? (If “Yes” then nonviable neonates may not be included in this research). Yes / No

3. Will vital functions of the neonate be artificially maintained? (If “Yes” then nonviable neonates may not be included in this research). Yes / No

4. Will the research terminate the heartbeat or respiration of the neonate? (If “Yes” then nonviable neonates may not be included in this research). Yes / No

5. Will there be added risk to the neonate? (If “Yes” then nonviable neonates may not be included in this research). Yes / No

6. Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means? (If “No” then nonviable neonates may not be included in this research). Yes / No

7. Does the informed consent process meet the requirements for inclusion of Nonviable neonates (Note: Waivers may not be applied)? (If “No” then nonviable neonates may not be included in this research). Yes / No

If the research does not meet the above requirements for the inclusion of nonviable neonates then the research may involve this population only by qualifying as “research not otherwise approvable” below.

Viable Neonates:

1. A neonate, after delivery, that has been determined to be viable is considered to be a minor. Does the research meet all requirements for the inclusion of minors in research (refer to determinations for the inclusion of minors in research)? (If “No” then viable neonates and other minors may not be included in this research). Yes / No

If the research does not meet the above requirement for the inclusion of viable neonates and other minors, then the research may involve this population.

Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material:

1. Is the research in accord with all applicable laws and regulations? (If “No” then the research is not approvable as proposed). Yes / No

2. Indicate which applies (If none, the research is not approvable as proposed):
   1. All information associated with these materials is recorded de-identified inclusive of identifiers link to individuals.
   2. All pertinent regulations and policies including consent requirements have been applied to all individuals that can be identified or linked with the material.

If the research does not fall entirely within the categories of question 2, or if the answer to questions 1 is NO, then the research may not be approved.

Research Not Otherwise Approvable:

1. Does the research present 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? (If “No” then the research is not approvable as proposed). Yes / No

2. Will the research be conducted in accord with sound ethical principles? (If “No” then the research is not approvable as proposed). Yes / No

3. Will informed consent be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part? (If “No” then the research is not approvable as proposed). Yes / No

If the answer to any of questions 1-3 is NO, then the research may not be approved. Note that if DHHS funded, the study may proceed only with approval from the Secretary of DHHS.

Comments and items to be addressed:
§46.205 Research involving neonates.

1. Where scientifically appropriate, have preclinical and clinical studies been conducted and data provided for assessing potential risks to neonates. (If “No” then neonates of uncertain viability may not be included in this research).

2. Individuals engaged in the research may have NO part in determining the viability of a neonate.

3. Which of the following categories applies? (If “Neither” then neonates of uncertain viability may not be included in this research):
   a. 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.
   b. 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.

4. Does the informed consent process meet the following requirements? (If “No” then neonates of uncertain viability may not be included in this research):
   a. Is 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 obtained in accord with subpart A of this part? (If “No” then neonates of uncertain viability may not be included in this research).
§46.207 Research not otherwise approvable

When research involving Pregnant Women, Fetuses and Neonates is not otherwise approvable the IRB may approve the study when it meets the following [Note that if the study is DHHS funded, it may proceed only with approval from the Secretary of DHHS]:

1. Does the research present 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 (If "No" then the research is not approvable)?
2. Will the research be conducted in accord with sound ethical principles (If "No" then the research is not approvable)?
3. Will informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part (If "No" then the research is not approvable)?