Pregnant Women or Fetuses Research Policy

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

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. 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 that cannot be obtained by any other means.

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

4. If the research holds out the prospect of
   a. direct benefit to the pregnant woman,
   b. direct benefit to the pregnant woman and the fetus, or
   c. no benefit for the woman or the fetus and 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.

   The woman’s consent is to be obtained in accord with the usual informed consent requirements of the federal regulations.

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 must be obtained in accord with the usual informed consent requirements of the federal regulations. The father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or if the pregnancy resulted from rape or incest.

6. Each individual providing consent under paragraph (4) or (5) of this policy is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

7. For minors who are pregnant, assent and permission are obtained according to the CCI/IRB policy on Inclusion of Minors in Research found at http://www.aecom.yu.edu/cci/page.aspx?id=9952