

DEPARTMENT: Yale University Human Investigation Committee  
POLICY NUMBER: XX.BB  
SECTION: Participation of Pregnant Women and Fetuses in Research  
REVIEW RESPONSIBILITY: IRB Leadership Committee and HIC Policy Review  
ORIGINAL CREATION DATE: May 31, 2006

## **Yale University School of Medicine HIC Policy Regarding: Participation of Pregnant Women and Fetuses in Research**

### **I. Purpose:**

This policy defines the standards for the participation of pregnant women/fetuses in biomedical, behavioral, and social science research. Research studies that involve pregnant women/fetuses should adhere to the regulations found at 45 CFR 46, Subpart B.

### **II. Definitions:**

Pregnancy: For purposes of this policy, the period of time from implantation until delivery.

Fetus: The product of conception from the time of implantation until delivery.

Neonate: A newborn.

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

Viable: Pertaining to neonates and for purposes of this policy, the ability, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable, it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of 45 CFR 46.

### **III. Policy Statement:**

Research involving women who are or may become pregnant requires special attention because of additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. The HIC will approve research involving pregnant women or fetuses if, in addition to meeting all other requirements, the research satisfies the conditions of 45 CFR 46, Subpart B, which are described below.

Research involving pregnant women or fetuses may be approved by the HIC if the following determinations are made and documented:

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;

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. Any risk is the least possible for achieving the objectives of the research;
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 to 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, the pregnant woman's consent is obtained in accord with the informed consent provisions of Subpart A;
5. If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father of the fetus is obtained in accord with the informed consent provisions of Subpart A, 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;
6. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children as defined in 45 C.F.R. § 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
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; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

Research that does not meet the above qualifications may only be conducted with approval of the Secretary of U.S. Department of Health and Human Services.

#### Guidance on Recruitment and Consent

1. Some pregnant women who are in active labor may be decisionally impaired because the physical and emotional stress of being in labor may affect their ability to understand information and make a reasoned decision about participation in a research study. [

2. In all research studies involving pregnant women, fetuses, or women who could become pregnant, the subjects should be informed of the potential risks to the fetuses that could result from the research. In studies involving pregnant women that are directed primarily toward maternal health, the subjects should be informed of the potential risks to the fetuses and also of any alternative treatments and their risks and benefits.