

Wayne State University Human Investigation Committee	
SUBJECT	The Inclusion of Pregnant Women in Research
Section	
Form Date	
Approvals	10/21/97 Steering Committee, 12/4/97 All IRB Committees, 4/25/98 Administrative

Background

Based on federal regulations described in Title VII of the Civil Rights Act of 1964 and Pregnancy Discrimination Act of 1978, it is illegal to discriminate against individuals on the basis of sex and/or pregnancy. By implication and logical extension, the *automatic* exclusion of pregnant women from research protocols is discriminatory and therefore illegal.

Sections of the Code of Federal Regulations (45 CFR 46.206(a)(2) and 45 CFR 46.207) also address some issues concerning the inclusion of pregnant women in clinical research. These regulations are clear when the protocol offers the possibility of saving a woman's life, but they are more general in other circumstances. The Code also states that the decision to participate is the woman's, but the father's consent should be obtained in some circumstances. It stipulates the circumstances under which a father's consent is not necessary. See HIC Policy/Procedure: "Research Involving Fetuses and Neonates" for related HIC policy.

HIC Policy

A pregnant woman cannot be excluded from a protocol if saving her life is even a remote possibility and *there are not other equivalent therapeutic alternatives*.

A pregnant woman may be excluded from a research protocol *IF* appropriate studies on animals and non-pregnant individuals have not been completed. The exceptions to this stipulation are as follows:

1. The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only the minimum extent necessary to meet such needs;

OR

2. The risk to the fetus is minimal.

When considering the health needs of the mother, the risk-benefit ratio of the research activity for the individual

and the fetus must be considered in the context of available alternatives.

HIC Policy for IRB Review of Protocols

Each protocol must be reviewed individually to determine whether the decision to include or exclude pregnant women in that particular study is appropriate in the context of available alternatives. The automatic exclusion of pregnant women (i.e. without a stated rationale) is not acceptable. Reviewers should ask the investigator for an explanation of the rationale for inclusion or exclusion if it is not given or it is not clear. The rationale must be scientifically justifiable. The following guidelines are to be followed in considering the inclusion of pregnant women in individual protocols:

1. If the protocol offers the chance of saving a woman's life, and there are not equivalent available therapeutic alternatives, she cannot be excluded from the study on the basis of her pregnancy.
2. If the protocol offers the chance of meeting the health needs of a woman **AND** the fetus will be placed at risk only to the minimum extent necessary to meet such needs, she cannot be excluded on the basis of pregnancy.
3. If the protocol would result in only minimal risk to the fetus, a woman cannot be automatically excluded on the basis of her pregnancy.

HIC Policy on Informed Consent

Once it has been determined that pregnant women may be included in a protocol, the decision to participate is the mother's (45 CFR 46.207) However, the father's consent should also be obtained **EXCEPT** under any of the following circumstances:

1. The purpose of the research is to meet the health needs of the mother and his refusal would interfere with this.
2. The father's identity or whereabouts cannot reasonably be ascertained.
3. He is not reasonably available.
4. The pregnancy resulted from rape.
5. The risk to the fetus is minimal.

The mother and father must be legally competent. If the father's consent is required, his signature should be added to the consent form; if not, the basis for the exception should be noted on the form.