POLICY ON THE USE OF WOMEN OF CHILD-BEARING POTENTIAL IN DRUG STUDIES

1. If there is a known likelihood of risk to a fetus, the Human Subjects Committee may require that women of child-bearing potential be excluded from participation.

   If however, there is a potential for direct benefit to the subject or overwhelming benefit to society, the Committee may approve the inclusion of women of child-bearing potential with stipulations that there be appropriate screening, monitoring, discussion, and informed consent.

2. If the likelihood of harm to a fetus is not known, the Committee may require the principal investigator to provide assurance (by pregnancy test or other appropriate criteria) that the women participating are not pregnant and instructions (via the consent process) on the necessity for the use of effective contraceptive measures if the study continues over a period of time.

Suggested Language For Consent Forms When Women of Child-Bearing Potential Are Involved.

1. If you are a female and capable of child-bearing, a sample of urine will be collected before the study is begun in order to be as sure as possible that you are not pregnant. It is important to be as sure as possible that you are not pregnant since the ... being tested may cause harm to an unborn child.

   or

2. If you are a female and capable of child-bearing, a sample of urine will be collected before the study is begun in order to be as sure as possible that you are not pregnant. Your participation requires that you use a birth control method, such as... to prevent pregnancy during the study, as the ... being tested may cause harm to an unborn child.

3. If you are female and capable of child-bearing, a sample of urine will be collected before the study is begun in order to be as sure as possible that you are not pregnant. Your participation requires that you use contraception methods (such as abstinence, diaphragm, condom, or an intrauterine device) to prevent pregnancy for the duration of the study, as use ... being tested may cause harm to an unborn child. If you miss a period or think you might be pregnant, you will notify the doctor. You may have to withdraw from the study.