Enrolling Men/Women of Childbearing Age

Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. Some research studies may need to ensure that non-pregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. A statement should be included about what the subject is expected to do to avoid pregnancy. If subjects can inadvertently become pregnant, the informed consent should state that the investigator and/or sponsor may periodically request information from the obstetrician/pediatrician to assess the development of the fetus/child.

If a research participant becomes pregnant during the study

If a subject that was advised to avoid pregnancy becomes pregnant after enrollment in a research study, the investigator is responsible for reporting this situation to the IRB immediately via an Adverse Event reporting form. Depending on study requirements, the subject may be withdrawn from the study. Any unintended pregnancies of participants in clinical trials should be reported to the FDA and study sponsor, as appropriate. The Sponsor and the Principal Investigator may periodically request information from the obstetrician/gynecologist and the child's pediatrician to assess the development of the child.

Male subjects

When appropriate, male subjects should be provided a statement that a particular treatment or procedure may involve risks to the sperm and consequently to the embryo or fetus which are currently unforeseeable as part of the informed consent process.

Contraception requirements

Requiring contraception in a clinical research protocol should be determined by the FDA drug classification of the investigational drug(s) used in the study:

FDA category A (no risk to fetus): no contraception required

FDA category B (no evidence of risk in humans, but risk in animals): the investigator may require contraception, but is not required to do so.

If contraception is required by the investigator, one reliable form of contraception is sufficient while on study and for a specified number of months afterward. Reliable forms are defined as condoms (with spermicide), diaphragm or cervical cap, intrauterine device, or hormonal contraception, as permitted by the study protocol.

FDA categories C (risk cannot be ruled out) and D (known risk to fetus): contraception is required for subjects engaging in sexual activity that could lead to pregnancy. Category C may require one or two forms of contraception, at the discretion of the investigator. For category D, two forms of contraception should be used.

If the category of the drug is unknown, investigators should follow the guidelines for category C drugs.