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Pregnancy and VA Research: Guidance on Collecting Data on Pregnancy and Outcomes of Pregnancy in VA Research Subjects and Pregnant Partners of VA Research Subjects

The VHA Office of Research and Development (ORD) has received questions from drug companies and investigators about collecting information on pregnant women when they are research subjects, research subjects who have withdrawn from the study or who have been terminated from the study, or pregnant partners of male research subjects. Many prescription and over-the-counter drugs used in clinical care are labeled as Pregnancy Category C by the FDA.* When Category C drugs are administered to women enrolled in research studies and these women then become pregnant, any information collection regarding the pregnancy or the outcome of the pregnancy must be included in the study protocol and informed consent, and the women must remain in the study while the information is being collected.

Below you will find some guidance on this issue:

Pregnancy is not an "unanticipated problem" if the protocol and/or the informed consent form mentions pregnancy as an exclusion factor, prevention of pregnancy, or what should be done if a pregnancy occurs.

Pregnancy is not an adverse event because it is not an unfavorable or unintended sign, symptom, or disease temporally associated with the use of the test article, and the pregnancy is not related to participating in the study. The exceptions are if the test article is designed to prevent pregnancy or interfere with birth control methods.

Congenital anomalies are serious adverse events (SAEs) that must be reported to FDA if they occur **during** the study.

Information can be collected on a research subject who becomes pregnant only if the IRB-approved research protocol, informed consent form, and data collection forms contain provisions for collection of information on the pregnancy, and the subject has provided consent in accordance with the IRB-approved consent process. Even if the protocol, informed consent, and data collection forms contain provisions for collection of information on the pregnancy, no further information can be collected if the woman's participation in the study is terminated or she withdraws from the study.

Pregnant partners. The research protocol, informed consent, and data collection forms must include provisions for collecting information from and/or about the pregnant partner, and the pregnant partner must provide consent in accordance with the IRB-approved consent process before any information can be collected from and/or about the pregnant partner.

Collecting data on the newborn infant. The investigator must not collect any information on the newborn infant unless the newborn infant becomes a research subject. Before collecting any information from the newborn infant, the investigator must include provisions for studying the newborn infant in the research protocol, the informed consent form, and data collection forms, obtain approval from the IRB, and then appropriate informed consent from the newborn infant's parent or legal guardian. A waiver from the CRADO must be obtained to enter the newborn infant into the study.

NOTE: *The concept of the newborn infant's being considered a research subject is analogous to the requirements for MedWatch reporting: If there is fetal death, miscarriage, or abortion, then the mother is the patient. However, if the child/fetus experiences a serious adverse event other than fetal death the child/fetus is the patient*.

Research informed consent. The IRB-approved research informed consent process must be applied to everyone from whom the investigator will collect data because these individuals are research subjects. The informed consent form must contain sufficient information to permit the individuals or their Legally Authorized Representatives to understand the risks and benefits related to their participation in the study. The informed consent form must specifically address collection of such information as alcohol use/abuse, use of elicit drugs, and history of sexually transmitted diseases.

NOTE: *If sensitive information is to be collected (e.g., alcohol or drug abuse, HIV status, etc.), obtaining a Certificate of Confidentiality from NIH is highly recommended.*

Type of data collected. Some drug companies are providing forms for the investigator to provide subject identifiers such as initials, date of birth, and/or name. Investigators must not provide these identifiers to the sponsor unless the sponsor provides a compelling justification. The investigator should consult with the local Privacy Officer and/or Information Security Officer about suitable justifications. In addition, some drug company forms include general requests for information (e.g., "relevant" lab results, "relevant" concomitant medications). The sponsor must be more specific and identify which lab results are to be collected and define the term relevant medications. The investigator must only submit information specified in the IRB-approved research protocol, the informed consent form, and data collection forms.

*Pregnancy Category C: Animal reproduction studies have shown an adverse effect on the fetus, but there are no adequate and well-controlled studies in humans.