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If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Link to Research Regulator

[Research Regulator](#) is a quarterly newsletter produced by the CASE Office of Research Compliance designed to disseminate to our community the most current and important information regarding the protection of human subjects in research. Each issue includes a one-credit CREC quiz, which can be completed online. If you would like to be added to the Research Regulator distribution list, please contact [Tracy Wilson-Holden](#), Education Administrator.

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Pregnant Women In Research

When do the regulations apply related to inclusion of pregnant women?

Based on feedback from the research community, additional guidance is being provided to clarify the required information for IRB review for the inclusion of pregnant women in research. It is important to note that if subjects become pregnant while enrolled in a research study, and data (including safety data) continues to be collected about them/their fetus/pregnancy, under the Federal regulations, they are considered to be research subjects. If the subjects are withdrawn and no data collected, they are no longer considered as research subjects.

What are the IRB requirements when pregnant women are research subjects?

The IRB requires that the following information be addressed in the protocol and consent document:

Discuss what happens if a female subject becomes pregnant while on the study:

- Will she be withdrawn with no further study intervention or interaction (includes all forms of data collection); or permitted to continue as per protocol; and
- For treatment studies in which the individual will be followed through the course of the pregnancy and beyond, the protocol and informed consent document must clearly indicate what will occur, including whether the study intervention will cease; what risks are involved; what additional follow-ups will occur; and when will the research end. All follow-up procedures that include the collection of data are considered research activities and the individuals are considered research participants. As such, you will need to:

1. Include a risk assessment for the inclusion of pregnant women under federal regulation 45 CFR 46.204 in the [protocol](#) (see UH Policy regarding the inclusion of pregnant women: <http://www.uhhospitals.org/Portals/6/docs/research/irb/IRBManual82005.doc>; and
2. Include a discussion in the main [consent form](#) regarding participation in this voluntary follow-up and indicate the parameters of the follow-up (how long, what information is collected) and clearly note that it is voluntary.

Examples for protocols and consent forms:

Below is suggested language to help address the required language needed in the research protocol and consent form relative for the inclusion of pregnant women in research. It should be amended based on each individual protocol (e.g., if data is to be collected about pregnant partners, language needs to be added to address their inclusion). **Please note that this is only an example.**

In the protocol: Inclusion of pregnant women

There is not enough medical information from preclinical studies to assess the potential risk-benefit ratio caused by the study intervention or procedures to pregnant women or the developing fetus, therefore pregnant women will not be included in the clinical intervention portion of the study. If a woman becomes pregnant, she will be removed from the study and transitioned to clinical care. However, the pregnant woman may be asked to participate in the collection of data regarding her health and the progress of the pregnancy, which meet the federal criteria for inclusion under 45 CFR 46.204. The study doctor will ask to collect information from the subject's OB/GYN about the pregnancy and every 4 months during the child's first year. This data collection does not pose more than minimal risk to the woman and no known risk to the fetus. Subjects will be fully informed at the time of consent about the foreseeable impact of the research on the fetus or neonate if they should become pregnant. Minors are not enrolled in this study therefore we will not enroll pregnant minors nor need to obtain assent. At no time will there be any inducements, monetary or otherwise, offered to terminate a pregnancy, nor will we take part in determining the viability of a neonate or in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

In the consent form: (basic language; *items in italics are the areas that will change depending on the type of clinical trial*).

"If you become pregnant during the study, you should contact your study doctor immediately; and you will be withdrawn from the study. Because there is no information on the effect of [*STUDY TREATMENT*] on pregnancy or the unborn child, *study doctor* will contact you *every 2 months* during the course of your pregnancy and will ask to follow the outcome of the pregnancy and condition of your newborn. *Information about your health and your pregnancy will be collected by the study doctor from your OB/GYN throughout your pregnancy and at the outcome of your delivery. Information collected will include: height/weight, last menstrual period, immunizations, exposure to alcohol or tobacco and delivery as well as the condition of your infant at birth (date of birth, weight, height, Apgar score) and for 12 months after birth (progression of growth during well child visits) for any significant medical issues.* This follow-up is voluntary."