From: OC GCP Questions
To: [redacted]
Subject: RE: Is Pregnant Partner a Research Subject
Date: Monday, April 07, 2014 1:32:15 PM

Dear [redacted],

I received your question about the need to obtain consent from female partners of male study subjects, in order to collect pregnancy outcome information.

> FDA regulations, 21 CFR 50.3(g), define a human subject as, "an individual who is or becomes a participant in research, whether as a recipient of the test article or as a control." In the scenario you describe neither the pregnant partner of the male subject nor the offspring of that pregnancy is receiving the test article or participating in the research as a control. Therefore, from FDA's perspective, neither the pregnant partner of a male subject nor the offspring of that pregnancy would be considered a human subject. However, FDA would consider the described activity as an important safety surveillance activity.
>
> That is not to imply that the pregnant partner should not be asked for her permission to provide private health information to a sponsor or submit this information to a registry. On both ethical and pragmatic grounds, asking for her permission would be appropriate, because obtaining medically valid information would likely involve the pregnant woman and her medical records as a source.
>
> FDA's industry guidance, "Establishing Pregnancy Exposure Registries" addresses this issue (as well as considerations for review by an IRB, considerations for registries involving newborn outcomes, and other related matters). Please see:
>
> http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071639.pdf
>
> As you note, 45 CFR 46, based on its differing authority and scope, contains a different definition of “human subject” than FDA’s regulations. According to 45 CFR 46.102(f), a human subject is "a living individual about whom an investigator conducting research obtains: 1) data through interventions or interaction with the individual; or 2) identifiable private information."
>
> Under HHS regulations, if privately identifiable information is collected in a registry on the pregnant partner of a male subject and the offspring of that pregnancy, then most likely the woman and the infant would be considered human subjects in the research. For research involving human subjects, informed consent would need to be obtained unless an IRB waived this requirement under 45 CFR 46.116(d). This regulation permits an IRB to approve a consent procedure which does not include, or which alters some or all of the elements of informed consent if it finds and documents: 1) the research involves no more than minimal risk to the subjects; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not practicably be carried out without the waiver or alteration; and 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. The above information reflects input from the Office for Human Research Protections (OHRP). If you have additional questions, we recommend that you contact OHRP directly. The main number is (240) 453-6900.

Sara F. Goldkind, MD, MA
Senior Bioethicist, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration
Tel: 301-796-8342; Fax: 301-847-8640
Email: Sara.Goldkind@fda.hhs.gov

From: [redacted]
Sent: Monday, April 07, 2014 9:15 AM
To: OC GCP Questions
Subject: Is Pregnant Partner a Research Subject

A male is participating in a clinical investigation of an investigational drug.

In the event his partner becomes pregnant, the sponsor wants to collect PHI about the partner's pregnancy. They want the pregnant partner to sign a consent document.

Is the partner a "human subject?" 21 CFR 50.3(g) defines a human subject as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient."

My opinion is that the pregnant partner is not a "human subject" and does not need to sign a consent document, but does need to sign a HIPAA Authorization.

Several on the IRB Forum feel that she is a human subject, but they cite Common Rule definitions.

Is there FDA guidance on this?

[redacted]