Considerations for Incidental Partner Pregnancy in Clinical Research: The Regulatory Landscape

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This article is the first in a two-part series that discusses informed consent and other considerations related to incidental partner pregnancies in clinical research.

There is often confusion among researchers and IRBs over how to handle the scenario in which a partner of a participant becomes pregnant during the course of a study. Collecting data on the partner can lead to critical safety information about the effects of the study compound; but what's often unclear is whether a pregnant partner is considered a research subject and how best to proceed with IRB review on this issue.

What Are the FDA and OHRP Regulatory Frameworks?

To develop a sound policy around pregnant partners, the regulatory framework of what constitutes a human subject under the federal regulations must be understood. FDA and OHRP require compliance with human subject protection regulations when human subjects become engaged in research subject to agency oversight.[1]

The FDA defines a human subject as:

An individual who is or becomes a participant in research, either as a recipient of a test article, or as a control. A subject may be either a healthy human or a patient.[2] FDA jurisdiction in this respect is focused on clinical investigations, defined as *any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration…or…the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.*[3]

OHRP, in comparison, more broadly defines a human subject as:

A living individual about whom an investigator conducting research obtains [either] (1) data through intervention or interaction with the individual, or (2) identifiable private information.[4]

Research under OHRP is also more broadly defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[5]

FDA oversight applies to all clinical investigations, while OHRP oversight applies when the research activity is federally funded or is conducted at an institution that applies the common rule to all its human subject research.[6]

How Does This Apply to Pregnant Partners?

IRBs vary in their interpretations of how to apply these regulations.

Generally, when the collection of pregnancy outcome data is **limited to safety surveillance**, neither the pregnant partner nor the infant is considered a human subject as defined by FDA.[7]

Rather, the collection of this information is done for surveillance purposes and is not part of the safety and effectiveness or marketing evaluation. Indeed, clinical protocols invariably implement contraception requirements and often call out anticipation of pregnancy as an exclusion criterion.

IRBs should closely evaluate the particular details of research to assess if OHRP oversight applies to pregnant partners.

Because researchers interact with—and collect identifiable information about—the pregnant partner and/or the infant, the collection of data relating to pregnant partners is often determined to constitute human subjects research that is subject to OHRP oversight.

A reasonable countervailing position is that pregnant partners are not a systematically studied or intentional study group. This leads some to the conclusion that the collection of pregnancy information, **when limited to safety surveillance**, does not constitute research that is subject to OHRP oversight.

The position taken depends upon the specific details of the circumstances and comfort level with regulatory interpretation, with the former position recommended in any instance of doubt or uncertainty. If the collection of pregnancy outcome data **transcends safety surveillance to become part of the clinical investigation**, is banked in a pregnancy exposure registry[8], or is otherwise performed for research purposes as defined by OHRP, IRB and informed consent requirements are warranted.

HIPAA

Since obtaining pregnancy outcome data involves the use protected health information (PHI) of the mother—and potentially the infant—HIPAA regulations apply.[9] Relevant authorization must be obtained, or waivers and alterations granted, because the use and sharing of this PHI is not otherwise for treatment, payment, or healthcare operation purposes.[10]

Policy Considerations

It is critically important to be mindful of the stress this situation can present to pregnant partners and study participants, and policies should be created with the regulations and the partner in mind.

Importantly, even in instances where informed consent is not required by regulation, it is still a good practice to fully inform pregnant partners and obtain their permission to collect pregnancy outcome data. FDA and OHRP regulatory elements of informed consent set a good standard and reflect the ethical tenets of respect for persons inherent in the research process.

Look for best practices and tips about the informed consent process in Part 2 of this series.