Background: When males are enrolled in clinical studies, researchers are often interested in evaluating whether the investigational drugs, devices, or procedures have effects on their female partners who become pregnant, the resulting fetus, and/or the newborn.

Is a pregnant partner a research subject?

Regulatory definitions:

Under HHS per 45 CFR 46.102:

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Under FDA per 21 CFR 50.3:

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects ...

(g) *Human subject* means 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.

(j) *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act ... 

The STANFORD IRB considers the pregnant partner and the neonate to be research subjects because the researcher is collecting identifiable private information (under HHS) and the partner and/or neonate is participating in the investigation by allowing the collection of information about his/her (indirect) receipt of the test article (under FDA). Therefore, the IRB will make findings under 45 CFR 46.204.

Pregnant Partner Consent Form

If the sponsor provides a consent form for the pregnant partner, ensure the HIPAA Authorization is included. The purpose listed on the HIPAA Authorization should be the collection of information about the pregnant partner and/or the fetus or neonate, **not** the purpose of the research in which the male partner is participating.

What Researchers Need to Submit to the IRB:

(1) Pregnant partner consent form in Section 13
(2) A HIPAA Authorization form (may be included in 1 above)
(3) A Report Form which is marked "Other events or information" (#7)

When to Submit to the IRB

The pregnant partner consent/HIPAA Authorization form should be submitted before any data is collected on a pregnant partner and/or fetus or neonate. It may be submitted with the initial study documents or at a later date when data collection is imminent, as long as enough time is allowed for IRB review and approval before its anticipated use.

The Report Form of a pregnant partner should be submitted after the pregnant partner is consented.