Background: When individuals are enrolled in clinical studies, researchers are often interested in evaluating whether the investigational drugs, devices, or procedures have effects on their pregnant partners and their fetuses. Pregnant partners who are not participants in the research should be consented for this purpose.

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

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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, fetus and child to be research subjects because the researcher is collecting identifiable private information (under HHS) and the partner, fetus and/or child 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.

When to Submit to the IRB

The pregnant partner consent/HIPAA Authorization form should be submitted as a modification to the approved protocol at the time a pregnant partner has been identified, prior to any data collection on the pregnant partner, fetus and/or child.

Additionally, a Report Form informing the IRB of the event should be submitted at the time a pregnant partner has been identified.

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) informing the IRB that the study now includes a pregnant partner

Pregnant Partner Consent Form

The pregnant partner consent form and HIPAA Authorization should state the purpose of the study as collection of information about the pregnant partner, fetus and/or child, **not** the purpose of the clinical investigation.