DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

COLLECTING DATA FROM PREGNANT PARTNERS
OF RESEARCH SUBJECTS
9/28/2021

As investigators are asked frequently to collect data on pregnancies that occur in partners of male subjects, study teams and the IRB have received many different methods and forms from sponsors for collecting this information. The state of being pregnant is protected health information (PHI) of the partner. Information regarding the outcome of the pregnancy and the health of the infant is PHI as well. According to 45 CFR 46, the partner/infant would be considered a human subject, if the PHI were to be used or disclosed for research purposes (see definition of "Research" below).

Under 21 CFR 50 the partner or infant would not meet the definition of a human subject, nor would the collection of this data be considered a clinical investigation as defined by 21 CFR 50.

When a pregnancy occurs in the partner of a research subject, this would be considered a safety event, but the DUHS IRB does not consider the partner to be a research subject (i.e., in most instances, collection of this information does not meet the definition of "Research" under 45 CFR 46). The collection of this PHI, though, does requires authorization from the pregnant partner.

45 CFR 46

> ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research
>
> (1) obtains information or biospecimens through intervention or interaction with the individual, and, uses studies, or analyzes the information or biospecimens, or
> (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
>
> ***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

21 CFR 50

> ***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.
>
> ***Clinical investigation*** means 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 under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but 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.

To provide guidance to study teams and sponsors, a template "Pregnant Partner Information Form" has been developed and is available on the IRB website in the Forms/Standard Language section. This form should be used in conjunction with the DUHS Authorization form (or the authorization form used by the pregnant partner's care provider) whenever a sponsor is requesting permission to collect information regarding pregnant partners. No information regarding the partner's pregnancy (accompanied with identifiers) should be recorded by the study team or the sponsor until the partner has given permission and signed the release form.

While the DUHS IRB views the collection of this information as an agreement between the sponsor and the pregnant partner, it is important to preserve the professional relationship that exists between the subject and the study team so the initial approach for permission must be via the subject (with his permission) and the Duke study team.

Below is the link for obtaining medical records at Duke, and downloading the DUHS Authorization Form in English or Spanish:

http://www.dukemedicine.org/patients-and-visitors/hospital-information/getting-medical-and-vitals-records

When the study team submits the IRB Pregnant Partner Information Form for a particular study in the electronic IRB system, the form should be filed in the "other study documents" section. It is not necessary to file the DUHS Authorization Form within the electronic IRB submission.

Previous Version Dates: 11/5/2014