Collecting Data from Pregnant Partners of Research Subjects

Purpose

This policy describes the process that needs to be followed when a researcher or sponsor wants to obtain data from pregnant partners of research subjects. This includes information about the pregnancy and child after birth.

Policy

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 pregnant female 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

(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 …

Boston Children's IRB

The Boston Children's Hospital 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).

Procedure

Written consent/authorization from the pregnant partner is required if data and information relating to the pregnancy will be collected from identifiable records. Obtaining consent requires talking with the male subject about the desire to obtain the information about the pregnant partner and the subsequent birth if applicable. 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 consent/authorization form.

It is important to preserve the professional relationship that exists between the subject and the study team so the initial approach for permission from the partner must be via the subject (with his permission) and the BCH study team.

A consent form for the pregnant partner must include the BCH HIPAA language .The purpose listed on the consent/authorization should be the collection of information about the pregnant partner, fetus and/or child, not the purpose of the research in which the male partner is participating. The pregnant partner consent/HIPAA Authorization form should be submitted before any data is collected on a pregnant partner, fetus and/or child. 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.

There needs to be the ability for a pregnant partner to "opt out" of additional data collection on his or her child. It is also important to specify in the consent form the time period requested for continued access to records regarding the pregnancy and birth. The time should not be open ended. Children have several steps of increasing autonomy which should correspond with decisions about use of their data. Providing parental permission to access their data in infancy requires defining the time frame. If there is long term follow up, reasonable expectations might include re-consenting the family at age 10-12 so that the developing autonomy of the child may be taken into consideration.

Special Pediatric/Adolescent Considerations

In a pediatric setting the pregnant partner may be a minor. Massachusetts statute, Chapter 112, Section 12F provides that "[a]ny minor may give consent to his medical or dental care at the time such care is sought if . . . (iv) she is pregnant or believes herself to be pregnant." The statute further provides that "[t]he consent of the parent or legal guardian shall not be required to authorize such care" and "[a]ll information and records kept in connection with the medical or dental care of a minor who consents thereto in accordance with this section shall be confidential between the minor and the physician or dentist, and shall not be released except upon the written consent of the minor or a proper judicial order."

Therefore, the (minor) pregnant partner may be contacted to provide consent for collection of information related to this pregnancy. The parent of this partner does not need to be contacted.

Please consult with the IRB as needed for study specific issues or situations not outlined in this policy.

Related Content

Regulatory Citation

FDA per 21 CFR 50.3:

HHS per 45 CFR 46.102

Massachusetts statute, Chapter 112, Section 12F

Document Attributes

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