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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

Collecting Data from Pregnant Partners of Research Participants Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Under Department of Health and Human Services (HHS) per 45 CFR 46.102:

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

Human subject: 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 biospecimen.

Under FDA per 21 CFR 50.3:

(c)Clinical investigation: 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. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

(g) Human subject: 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 or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

Policy Statements

This policy describes the required process when a researcher or sponsor wants to obtain data from pregnant partners of research participants. When individuals are enrolled in clinical studies, researchers are often interested in evaluating whether the investigational drugs, devices, and/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. This includes information about the pregnancy and child after birth.

The Boston Children's Hospital Institutional Review Board (IRB) considers the pregnant partner, fetus, and child to be research participants 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 their (indirect) receipt of the test article (under FDA).

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."

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

Procedures

Pregnant partner consent forms should not be submitted as part of the initial New Research Application to the Boston Children’s Hospital IRB. A pregnant partner consent form should only be submitted to the IRB via an amendment when a known pregnant partner has been identified. The IRB administrative office

may review these documents via the expedited procedure or by the Convened Committee, as necessary.

1. Written consent/authorization from the pregnant partner is required if data and information relating to the pregnancy will be collected from identifiable records and must include the Boston Children's HIPAA authorization language.
2. 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.
3. 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 partner is participating.

Identification and Consent of a Pregnant Partner

1. When a participant informs the investigator of their partner's pregnancy, the investigator must inform the IRB and submit an amendment to have the pregnant partner consent form approved.
2. It is important to preserve the professional relationship that exists between the participant and the study team.
    a. The initial contact for permission from the partner must be via the study participant (with their permission) and the Boston Children's Hospital research study team.
    b. Obtaining consent requires talking with the study participant about the desire to obtain the information about the pregnant partner and the subsequent birth if applicable.
3. If the study participant...
    a. Refuses to contact the pregnant partner or if the pregnant partner refuses to sign the pregnant partner consent form, no further contact will be attempted. The refusal must be documented in the study record.
    b. Signs the partner consent, the consent process should be documented in the study participant's research record. The treating investigator/study team will then report the pregnancy to the sponsor per the protocol.
4. There needs to be the ability for a pregnant partner to "opt out" of additional data collection on their child.
5. It is also important to specify in the consent form the time period requested for continued access to records regarding the pregnancy and birth.
    a. The time limit should not be indefinite.
    b. Providing parental permission to access their child's data in infancy requires defining the time frame.
    c. Children experience several developmental steps associated with increased autonomy, which should align with their ability to make decisions regarding the use of their data.
    d. If there is long term follow up, a reasonable expectation might include re-consenting

the family at age 10-12, so that the developing child's autonomy may be taken into consideration.

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

Related Content

- Department of Health and Human Services Regulations: HHS 45 CFR 46.102
- U.S. Food & Drug Administration: 21 CFR 50.3
- Commonwealth of Massachusetts General Laws: 112 Section 12F

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	5/14/2024
Site Administrator: Education/ Training Requirement	Dwight Mayfield	5/13/2024
Steering Committee	Dwight Mayfield	5/13/2024
Required Departmental Review/Approval	August Cervini	2/15/2024
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Applicability

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