3.11 Collecting Data from Pregnant Partners of Research Subjects

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for obtaining informed consent, and collecting data from pregnant partners of research subjects and from their infants.

2.0 Policy

- **2.1.** It is the policy of the organization that collection of identifiable private information about the pregnant partner of a research subject, or obtaining data about that subject through interaction with her, constitutes human subject research under 45 CFR 46, and is subject to the requirements of those regulations and of the HRPP.
- **2.2.** It is the policy of the organization that collection of identifiable private information about the infant child (up to 3 months of age) conceived during the time that the mother was a partner of a research subject, or obtaining data about that child through interaction with the child, constitutes human subject research under 45 CFR 46, and is subject to the requirements of those regulations and of the HRPP.

3.0 General Considerations

- **3.1.** There is considerable variation between IRBs regarding the interpretation of HHS and FDA regulations in respect to pregnant partners of research subjects. Generally, when the collection of pregnancy outcome data is limited to safety surveillance, neither the pregnant partner nor the infant is considered a human subject under FDA regulations. However, because researchers collect identifiable information about, and interact with, the pregnant partner and/or the infant, the collection of data in this context appears to constitute human subjects research under HHS regulations and the Common Rule.
- **3.2.** Since obtaining pregnancy outcome data involves the use of protected health information of the mother and possibly the infant, the use and sharing of this information is subject to the HIPAA Privacy Rule. Consequently, authorization must be obtained, or waivers of authorization granted, as per regulation and HRPP policies 5.1 (Obtaining Informed Consent form Research Subjects) and 5.2 (Waiver or Alteration of Informed Consent and HIPAA Authorization).

- **3.3.** Collection of pregnancy outcome data that is part of the clinical investigation, or is banked in a pregnancy exposure registry, constitutes human subject research, and is subject to HHS and/or FDA regulations.

4.0 IRB Review

- **4.1.** Under most circumstances, protocol for collection of pregnancy outcome data should be submitted to the IRB on a Medical Records Research application.
- **4.2.** If there is a high likelihood that subjects or partners of subjects will become pregnant during the course of the research, the collection of pregnancy outcome data may be included in the initial submission of the protocol.
  - **4.2.1.** The IRB application must include relevant information concerning the pregnant partners and the infant (if applicable) as subject populations distinct from the primary subject of the research. The application must include a thorough description of the specific data to be collected regarding the pregnant partner, and the infant (if applicable), how privacy and confidentiality will be protected, how potential subjects will be identified and recruited, and how informed consent will be sought and documented
- **4.3.** Federally funded research must satisfy requirements of subpart B. Non-Federally funded research must be no more than minimal risk to mother and fetus, and satisfy requirements of HRPP policy 4.2: Research Involving Pregnant Women, Human Fetuses, and Neonates (Nonviable or of Uncertain Viability).
- **4.4.** Federally funded or FDA regulated research must satisfy requirements of subpart D (45 CFR 46.404 and/or 21 CFR 50.51) if information about the infant is collected.
- **4.5.** The Medical Records Research application may be reviewed through an expedited process (per HRPP policy 2.3; Expedited Review) provided it constitutes no more than minimal risk

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5.0 Informed Consent

- **5.1.** Informed consent must be obtained and documented from the pregnant partner in accordance with HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects).
- **5.2.** If pregnancy outcome data includes identifiable private information regarding the infant, Parental permission must be obtained in accordance with HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects). A separate “Parental Consent Form” is not required; the Pregnant Partner consent form should be structured such that it includes information relevant to the infant, and the partner’s signature on that form signifies her permission

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