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**Boston
Children's
Hospital**

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Applicability Boston Children's
Hospital- Policies
& Procedures

Sex Assigned at Birth, Birth Control, and Pregnancy Testing Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy indicates that investigators are required to be inclusive with sex assigned at birth in study populations for research findings to be a benefit to all persons at risk of the disease, disorders, or conditions.

It also provides guidance for birth control requirements and pregnancy testing in clinical trials.

Policy Statements

Clinical investigators are required to be inclusive of sex assigned at birth in study populations for research findings to be a benefit to all persons at risk of the disease, disorders, or conditions.

Research involving persons who may become pregnant during research interventions require special attention from IRBs, because of the additional health considerations during pregnancy and the need to avoid unnecessary risk to the fetus.

As a pediatric institution, there are additional sensitive issues that may arise regarding the requirement for pregnancy testing.

Current Clinical Standards

Boston Children's Hospital requires that each clinical department implement a departmental policy regarding pregnancy testing. Investigators are responsible for being knowledgeable about department's standards as it pertains to the assessments and procedures in the research.

Procedures

Inclusion

If one sex assigned at birth is excluded or is inadequately represented in a study, a clear, compelling scientific rationale for exclusion or inadequate representation is to be provided in the protocol.

That the effects of a drug on a fetus are unknown is not an acceptable rationale for excluding persons of childbearing potential, as mechanisms for the prevention and monitoring of pregnancy are available.

Birth Control Requirement in Clinical Trials

The Institutional Review Board (IRB) is often asked to approve protocols for investigational drugs that require persons of childbearing potential to use a specific method of birth control (e.g. oral contraceptives, IUD). Although the need to prevent pregnancy in subjects who participate in such studies is medically justified because of the unknown risks of the drug to fetuses; the requirement for a particular method of birth control is generally unaccompanied by a legitimate medical rationale, and has the undesirable and improper effect of precluding participation in the study by persons who use methods of birth control that differ from those specified in the protocol (e.g., abstinence).

To remove the discriminatory effect created by protocols that specify particular methods of birth control, the IRB adopted the following guidelines:

1. Eligibility for participation in a study may not be based on a subject's agreement to use a specific birth control method unless there is a legitimate medical or scientific reason why the use of other birth control methods are unacceptable (i.e. investigational drug interaction with birth control pills).
2. If the protocol specifies the type of birth control method to be used, the medical or scientific reason(s) must be set forth in the protocol and approved by the IRB.

Pregnancy Testing

In research studies that involve persons of childbearing potential, appropriate precautions are to be taken to guard against inadvertent exposure of fetuses to potentially toxic agents during clinical research.

Research that involves anesthesia, surgery, chemotherapy, pharmaceutical agents, high dose ionizing radiation, multiple diagnostic x-rays, and radioactive isotopes of iodine all may potentially harm a fetus. For this reason, pregnancy testing may be used to detect unsuspected pregnancy prior to initiation and during the research. When required, subjects are to be informed about the need to avoid pregnancy

during the research. In some situations, partners may need to be informed that they are to avoid inseminating a subject while participating in a research protocol.

Special Pediatric/Adolescent Considerations

As a pediatric institution, there are additional sensitive issues that may arise regarding the requirement for pregnancy testing. These are as follows:

1. Potential subjects may be at various stages of puberty. Because the beginning of menses is unpredictable, subjects may begin menstruation at any time during the research.
2. Although very unlikely, a subject could become pregnant prior to the onset of menses.
3. Many subjects who have begun menses are not sexually active.
4. Menses now begins at younger ages.
5. Parents may not be aware of their child's sexual activity.
6. The assent of the child/adolescent and the permission of the parent are required in many research protocols.

IRB Guidelines

The following IRB guidelines for pregnancy testing are implemented as part of a research protocol:

1. An investigator's plan for pregnancy testing is to be consistent with the clinical guidelines unless a justified exception is approved by the IRB and the Department Chair or Division Chief.
2. Protocols may not exclude persons based upon their potential to bear children. There must be justified, scientific rationale to exclude persons of childbearing potential.
3. Massachusetts law requires that a positive pregnancy test result be communicated only to the minor and not to their parents without permission. This includes pregnancy test results obtained during the course of research.
4. The IRB sets an age criterion of 12 years or the onset of menses, as a requirement for pregnancy testing in protocols that may potentially affect a fetus.
 - a. If an investigator proposes to perform pregnancy testing for children under the age of 12 or before the onset of menses, the investigator must justify why this is appropriate for the protocol.
 - b. In determining whether it is acceptable to perform pregnancy testing before age 12 or the onset of menses, the IRB considers the potential for direct benefit offered by the protocol within the context of the research.
5. **Adolescents under the age of 12:** For subjects under the age of 12 (if required by the protocol), the investigator is to use their discretion as to the subject's knowledge of and exposure to sexual activities in order to determine whether a separate document is reasonable.
6. **Adolescents age 12 and older:** The IRB strongly recommends that investigators consider the use of a separate document for adolescents age 12 and older, even when assent is not required by the adolescent. This document is to address pregnancy testing and the need to avoid pregnancy only.

7. Any plan for pregnancy testing must be fully disclosed in the informed consent document. The consent is to include:
 - a. The type of pregnancy testing (blood or urine).
 - b. The frequency of testing (prior to the trial, during, both).
 - c. What will happen if results are positive?
 - d. Who will be informed of the results?
 - e. How confidentiality will be maintained?

Sample consent form template language describing pregnancy testing is available.

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures

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