Women

Policy

Inclusion of Women in Research

- Clinical investigators are required to include both genders in study populations in order for research findings to be of benefit to all persons at risk of the disease, disorder, or condition under study.
- This policy applies to all research that involves human subjects and human materials, and it applies to males and females of all ages. If one gender 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 women of child bearing 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 women of child bearing potential to use a specific method of birth control (e.g., oral contraceptives, IUD). Although the need to prevent pregnancy in female 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 women 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:

- Eligibility for participation in a study may not be based on a subject's agreement to use a specific method of birth control unless there is a legitimate medical or scientific reason why the use of other methods of birth control is unacceptable (e.g., investigational drug interaction with birth control pills). 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 women of child bearing potential, appropriate precautions are to be taken to guard against inadvertent exposure of fetuses to potentially toxic agents during the course of 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 course of the research. When required, subjects are to be informed about the need to avoid pregnancy during the course

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of the research. In some situations, males may need to be informed that they are to avoid inseminating a female 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:

- 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 course of the research.
- Although very unlikely, a subject could become pregnant prior to the onset of menses.
- Many female subjects who have begun menses are not sexually active.
- Menses now begins at younger ages.
- Parents may not be aware of their child's sexual activity.
- The assent of the child/adolescent and the permission of the parent are required in many research protocols.

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 their department's standards.

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 specified by his or her department, unless a justified exception is approved by the IRB and the Department Chair or Division Chief.
2. Protocols may not exclude females based upon their potential to bear children. There must be justified, scientific rationale to exclude women of child bearing potential.
3. Massachusetts law requires that a positive pregnancy test result be communicated only to the minor, herself, and not to her parents without her 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. 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 particular protocol. 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. Any plan for pregnancy testing must be fully disclosed in the informed consent document. The consent is to include:
   - the type of pregnancy testing (blood or urine).
   - the frequency of testing (prior to the trial, during, both).
   - what will happen if results are positive.
   - who will be informed of the results.
   - how confidentiality will be maintained.
   - Sample consent form template language describing pregnancy testing is available.

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6. 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. For subjects under the age of 12 (if required by the protocol), the investigator is to use his or her discretion as to the subject's knowledge of and exposure to sexual activities in order to determine whether a separate document is reasonable.

Related Content

Document Attributes

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Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		

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