

# Pregnancy Testing and Contraceptive Use for Research Studies- IRB Guidance

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## Summary

Current clinical standards at Children's for pregnancy testing and use of contraceptives: All female patients of child-bearing potential, defined as age 12 or greater or having started menses, receiving non-emergent anesthesia, deep sedation, designated non-urgent radiological procedures or chemotherapy for cancer treatment will be screened for pregnancy prior to the initiation of treatment unless the physician determines and documents that such screening is not medically necessary. Please see Policies 1.09 and 2.36 Pregnancy Screening for more detailed information.

## Guideline:

- The research plan for pregnancy testing should be (consistent with or no less stringent than) the clinical guidelines specified by his or her department, unless a justified exception is approved by the IRB and the department.
- Protocols may not exclude females based on their potential to bear children. There must be justified, scientific rationale to exclude women of childbearing potential.
- 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 a protocol proposes to perform pregnancy testing in children under the age of 12 years or before the onset of menses, the investigator must justify why this is appropriate for this protocol. When reviewing requests for pregnancy testing before age 12 or the onset of menses, the IRB will consider the potential for direct benefit offered.
- Plans for pregnancy testing must be fully disclosed in the informed consent. The consent must include:
  - Type of pregnancy testing (blood or urine)
  - Frequency of testing (prior to treatment, during or both)
  - How positive results are shared (i.e., who will be informed)
- The IRB strongly recommends the use of a separate assent document that addresses only pregnancy testing and the need to avoid pregnancy.

## Questions

Contact the [IRB](#) at [irb@choa.org](mailto:irb@choa.org)