

SOP 805: Pregnancy Testing in Research Subjects**SOP****I. PURPOSE**

The purpose of this SOP is to describe the requirements for pregnancy testing in research subjects.

II. POLICY STATEMENT

It is the policy of the IRB that research study materials which involve procedures that could adversely affect pregnant women or fetuses should include protections to avoid the inclusion of pregnant women as research subjects.

III. SCOPE

This policy applies to all IRB staff, IRB members, and investigators and their staff who propose and conduct research involving individuals who are or may become pregnant.

This only applies to studies involving procedures/ interventions that could potentially have an adverse impact on pregnancy or the fetus.

IV. DEFINITIONS

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Pennsylvania, persons age 18 years or older can consent to their own medical, dental and health care. Pennsylvania law also allows persons under the age of 18 years to consent to a wide variety of medical testing and treatment and health care services. [See, CHOP "Patient Care Manual: No. RI-5-01, Consent and IRB SOP 505].

Fetus: The product of conception from implantation to delivery.

Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Minor: A person who has not yet reached the age of majority in the state where the research is conducted.

POCT: Hospital Point-of-Care Testing, which is Laboratory testing performed at the Main Campus outside the physical facilities of the Department of Pathology and Laboratory Medicine, under the Hospital CLIA and lab license. The Laboratory Director (Pathologist-in-Chief and Chair, Department of Pathology and Laboratory Medicine) is responsible for POCT. [See CHOP policy Point-of-Care & Physician-Office-Laboratory Testing]

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Pregnancy: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. A postmenarchal female patient is considered pregnant if she states she is pregnant or is confirmed to be pregnant via urine or serum pregnancy testing (Radiology Policy).

Principal Investigator: The individual at each institution personally responsible for the overall conduct of a specified human subjects research study or clinical investigation.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). Under FDA regulations, research (clinical investigation) means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects.

IRB Reviewer: The Chair, CPHS or their designee who is responsible for providing a review of all submitted materials (described in SOP 301), documenting the review on the appropriate evaluation form, and taking an action on behalf of the IRB. The reviewer must be an experienced IRB member/alternate.

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1. The study materials should address the interventions with the potential to adversely affect a pregnancy or the fetus.

For example, certain study medications administered during a pregnancy may be associated with adverse outcome(s) of the pregnancy itself (e.g., miscarriage) or adverse outcome to the fetus (e.g., birth defect, poor growth, or others).

2. The age criteria of 11 or the onset of menses (whichever occurs first) should generally be a requirement for pregnancy testing in study materials having the potential for adversely affecting a pregnancy or the fetus.

3. The consent form submitted with study materials should inform potential subjects about the need to avoid pregnancy and appropriate methods of pregnancy prevention (e.g., abstinence, reliable contraception methods, etc.) as applicable. Methods to avoid pregnancy for subjects biologically capable of impregnating a person or becoming pregnant should both be included, as applicable.

B. Research involving only procedures routinely performed as part of clinical care

1. For research procedures which are routinely performed in clinical practice (e.g., MRIs, CT scans, etc.), the study materials should outline whether pregnancy testing will be performed or if the department's standard operating procedures for pregnancy screening will be followed.

(a) For example, if a research study involves an MRI with both FDA approved and non-FDA approved sequences, the investigators should outline whether pregnancy testing will be performed or Radiology's standard operating procedures (Pregnancy Screening and Testing for Radiology Exams and Procedures in Female Patients of Child Bearing Age) will be followed.

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1. For studies involving pregnancy testing, the details of the pregnancy testing, including who will be tested, what type of test will be used (urine or serum), and what will happen if the results are positive should be outlined in the study materials.
2. Pregnancy testing (using urine or serum) may be completed in a CLIA approved lab or through an appropriate POCT mechanism.
3. Pregnancy testing must only be conducted by individuals who are appropriately credentialed to perform the test, by the institution where the test is being performed. [SEE CHOP Policy Point-of-Care & Physician Office Laboratory Testing].

D. Return of pregnancy test results

1. If a pregnancy test result for a minor in the state of Pennsylvania is positive, the results must be provided to the pregnant minor, not her parent or guardian, unless the pregnant minor would be unable to understand the results (e.g., due to cognitive deficits). When CHOP is serving as the reviewing IRB for sites outside of Pennsylvania, local laws pertaining to results of pregnancy testing will be followed.
2. All institutional policies related to return of pregnancy test results must be followed (e.g., returning pregnancy test results to a subject's medical record as required per institutional policy, etc.).
 - (a) At CHOP, any diagnostic or laboratory test performed at CHOP using the same methods, personnel and facilities as those ordered by a clinician during the course of clinical care should be recorded in the patient health record.

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VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.204	Policy: Pregnancy Screening and Testing for Radiology Exams and Procedures in Female Patients of Child Bearing Age
Policy: Adolescents – Reporting Requirements for STIs, Pregnancy and Consent and Confidentiality Issues	Policy: Point-of-Care & Physician-Office-Laboratory Testing
Policy: Patient Health Records	

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 502: Research Involving Pregnant Women, Fetuses, and Neonates	SOP 505: Minors Who Are Not Children in the Research Context
SOP 903: Reporting Test Results and Incidental Findings	

VIII. RESPONSIBILITIES

Title	Responsibility
Principal Investigator	Responsible for providing a sufficient plan to avoid pregnancy in research subjects if the procedures have the potential to adversely affect the pregnant woman or fetus.
IRB Reviewer	Responsible for reviewing the submitted materials and plan regarding pregnancy testing and ensuring that the plan is appropriate and complies with all applicable state laws.

IX. ATTACHMENTS
X. REVISIONS:

06-07-2021: Initial approval date

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XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/07/21

Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, IRB Research