

## I. PURPOSE

The purpose of this standard operating procedure is to clarify the responsibilities of investigators for reporting incidental findings from tests or procedures performed for research purposes. Whenever test results might be reported to subjects or their physicians, the policy establishes the requirements for certification of laboratories and test facilities and the personnel performing and reporting test results.

## II. POLICY STATEMENT

It is the policy of the Institutional Review Board at Children's Hospital of Philadelphia that investigators communicate all clinically significant test results to subjects or their parents. Only individuals who are appropriately certified or licensed to interpret the test results may communicate the results to subjects. Laboratory results that will be communicated to patients or their parents must be performed (or repeated) in a CLIA-certified laboratory, performed using FDA-approved radiologic equipment and software or, in the case of psychological tests, performed by certified professionals.

## III. SCOPE

These policies and procedures apply to all investigators.

## IV. DEFINITIONS

CLIA: Clinical Laboratory Improvement Amendments (1992) established standards for accuracy and precision of laboratory tests. Certification is required for all clinical-diagnostic laboratories.

Clinically Significant: Results that are scientifically valid, have been confirmed by a medically established diagnostic product or procedure and where the knowledge of the test result will alter the course of current treatment or result in the initiation of a currently available, validated therapy. To be clinically significant, the test procedure must have established accuracy, precision, and reproducibility (e.g., a lab test must be performed in a CLIA-certified laboratory, imaging must be of clinical quality, MRI sequences must be FDA-approved).

## V. PRINCIPLES

Any clinically significant test result must be communicated to the subject or subject's parent, depending on the age of the subject and type of testing. The timeliness should be appropriate to the nature and urgency of the clinical information being communicated. The study team must release the clinically significant results to the primary care physician, where appropriate authorization has been obtained. The study team, at a minimum, should also refer the subject to an appropriate provider for further clinical care and/or counseling as indicated by the nature of the test result.

Investigators should not divulge the results of non-validated tests or procedures or the

results of laboratory studies performed in non-CLIA labs. Non-validated tests and procedures that are of uncertain significance include, but are not limited to, genetic testing without known implications (such as linkage analysis), functional MRI scans or other tests/procedures that are without established diagnostic or treatment value.

In the case of psychological and neuropsychological testing, investigators with backgrounds in communicating such results are expected to communicate these test results to the families and/or subjects. If psychological or neuropsychological testing will be performed and the results will be disclosed, the person performing the test and the person disclosing the results must possess the relevant certification.

## **VI. PROCEDURES**

### **A. Reporting Results to Individuals**

If a diagnostic test, performed during research, will be made available to subjects or their physicians, the tests must be performed in a CLIA-certified laboratory, unless the FDA has issued a waiver. CLIA provides for “waivers” that allow certain simple tests to be performed outside a clinical laboratory, but the testing site must obtain a Certificate of Waiver and meet other CLIA requirements. Researchers should consult with experts in the CHOP Clinical Laboratories for details of the CLIA requirements. Researchers should consider how the benefits of providing results weigh against the risks of doing so.

### **B. Withholding Results from Individuals**

1. Validated laboratory tests performed at a time distant to when the samples are obtained, may, in the investigator’s judgement, no longer be clinically relevant. The research plan should specify when this situation will apply.
2. If novel or experimental tests, including genetic tests, will be performed outside of CLIA-certified auspices, or performed using an investigational device (e.g., an unapproved MRI sequence), the investigator may not utilize the test results for clinical decision-making.
  - (a) In such cases, applications for IRB review should indicate clearly that specific results will not be provided to subjects or their physicians, and the study consent form should also explain the reasons for not reporting.
  - (b) If an experimental test or procedure performed during research is subsequently validated, the investigator may offer the opportunity for the participant to have the test repeated in a certified laboratory or facility.

### **C. Consent Issues**

1. In accordance with the 2018 Common Rule (45 CFR 46.116(c)(8)), the consent form will include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if

so, under what conditions.

2. Consent forms should discuss the treatment implications of diagnostic tests, especially when the test is experimental or when the test results will not be available for some time or when there is no clear course of recommended treatment.
3. If test results might reveal a condition not previously documented in a patient's medical records, the consent form should discuss the risks, e.g. implications for the insurability of the participant, if test results were to be disclosed.
4. Research data will be entered into the CHOP medical record in accordance with CHOP Policy: Patient Health Records.
5. Subjects must be informed of the extent to which the results of tests and procedures, that are not required for their continuing clinical care, will be kept confidential. In general, access to these results should be limited to investigative team members and those parties listed on the informed consent form (FDA, IRB, monitors representing the study sponsor, etc.)

## VII. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs

CHOP Policy: Patient Health Records

## VIII. RESPONSIBILITIES

<b>Title</b>	<b>Responsibility</b>
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.

## IX. ATTACHMENTS

APPENDIX: Ethical Justifications for Providing Results in the Absence of CLIA Certification

## X. REVISIONS:

- 09-08-2006 Minor editorial revisions by Deputy General Counsel.
- 11-10-2006 Revised to state samples sent to a foreign lab must be sent ONLY to a CLIA-certified lab.
- 06-10-2010 Revised to correct minor grammatical issues for consistency across SOPs.
- 03-11-2013 Revised to include the results obtained using investigational devices.
- 12-13-2022 Revised to reflect current policies and regulations.

## XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/13/22  
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS