INTRODUCTION

Research data and clinical data can overlap. Additionally, research data may have implications for clinical care and provide insightful information for the management of a study subject who is also a patient at The Children’s Hospital of Philadelphia (CHOP).

POLICY STATEMENT

Based on CHOP’s adoption of an electronic medical record (EMR) and the ultimate concern for patient safety, it is the policy of The Children’s Hospital of Philadelphia Research Institute that patients’ medical records include research subject information that impacts clinical care, as it relates to the medical care, treatment and services provided to the patient as part of a research study.

PURPOSE

The purpose of this policy is to define the research data that should and should not be entered into the medical records systems (i.e., Epic, ChartMaxx, and others as applicable) at The Children’s Hospital of Philadelphia.

SCOPE

This policy applies to all study subjects whose research data may impact clinical care, or who are also patients at The Children’s Hospital of Philadelphia.
GUIDELINES FOR RESEARCH DATA IN CHOP’s MEDICAL RECORDS

- The following research data **should be recorded** in the CHOP medical record:
  - 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.
  - Any laboratory test processed by CHOP clinical laboratories and sent to an outside CLIA certified laboratory with results sent directly to the clinical labs for data entry.

- The following research data **may be recorded** in the CHOP medical record at the Principal Investigator’s discretion:
  - Laboratory studies from a CLIA certified laboratory.
  - Diagnostic testing performed by certified ancillary staff such as psychologists, genetics counselors or technicians.

- The following research-specific tests **should NOT be recorded** in the participant’s medial record:
  - Any tests results obtained/received from a non-CLIA certified laboratory.

SPECIALLY PROTECTED INFORMATION

Specially protected information can raise concerns for research participants and study staff. The Hospital has detailed processes for safeguarding such data and these processes and policies must be adhered to at all times. Specially protected information includes:

- Mental health (MH) information
- HIV status
- Drug and/or Alcohol (D&A) Abuse or Dependence
- Title X-funded Family Planning Services
- Genetic information
- Services minors can consent to on their own under state law including pregnancy and STD testing/treatment, and other limited services
- Services provided to a minor under a parental agreement of provider/patient confidentiality
PATIENT RECORD ACCESS

Regardless of the information that is being recorded in the medical record, it is important to remember the following:

- All clinicians must be able to access all sections of the patient record (except some Title X service documentation) for purposes of treatment
- Select groups of the CHOP workforce must be able to access all sections of the patient record (except Title X services) for purposes of payment and health care operations activities.

DEFINITIONS

**ChartMaxx** – CHOP’s enterprise-wide legal medical record for inpatient, emergency department, day surgery, day medicine and twenty-three hour (TTH) stay visit types.

**Epic** – CHOP’s integrated electronic health record application.

RELATED POLICIES AND PROCEDURES

- [CHOP’s Scanning and Importing Documents into Epic in Ambulatory Settings](#)
- [CHOP’s Clinical Documentation Guidelines For Patient Health Records](#)
- [CHOP’s Patient Health Records](#)
- [CHOP’s Release of Information (Toolkit)](#)

WHO SHOULD BE KNOWLEDGEABLE ABOUT THIS POLICY

Those who are responsible for following the guidelines/performing the procedures that implement this policy, those who have the oversight and/or supervisory responsibility for these guidelines/procedures, and those who have the responsibility to authorize this policy and its related processes/procedures should be knowledgeable about this policy.
POLICY MAINTENANCE RESPONSIBILITY

**Policy Owner:** Research Compliance and Regulatory Affairs

**Policy Contact:** Deb Barnard, Director of Research Compliance and Regulatory Affairs

POLICY AUTHORIZATION

**Approved by:** Approved by Leadership on 06/06/12

CHOP Research Executive Leadership

VERSION/REVISION HISTORY

Reassessment of this policy will occur at least once every 24 months; interim revisions will be incorporated as needed. The table below documents the version/revision history for this policy. A cumulative history for this document is maintained for seven years.

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