

Guidance for Submission of Research Related Documents to Stanford Children's Health for Inclusion in the Electronic Patient Medical Record

Purpose: The purpose of this document is to clarify what research-related documents should be submitted to Stanford Children's Health (SCH) for inclusion in the electronic patient medical record. This document also sets forth the current process for how to submit these documents to SCH's medical records department (HIMS)

The following research-related documents should be recorded in the electronic patient medical record:

- Signed informed consent documents for any studies with interventional (drug/biologic/device/surgical/diagnostic) interventions that will be taking place at Lucile Packard Children's Hospital (LPCH) or in LPCH-licensed space
- Signed informed consent documents for behavioral/observational study that is taking place at LPCH or in LPCH-licensed space
- Any consent-related documents signed during a medical encounter at LPCH or in LPCH-licensed space
- Signed informed consent documents for any studies where study activities will take place at LPCH or in LPCH-licensed space
- Signed informed consent documents for any studies where study activities will impact the patient's plan of care
- Any lab results that inform or impact the patient's plan of care
- Documentation that reflects the care provided to or diagnostic assessment of the patient; exceptions must be described in the research consent, e.g., genetic tests, non-validated or non-CLIA approved test results or confidential data which must be protected.

Submit the above documents to HIMS for upload into the electronic patient medical record within 48 hours of obtaining:

1. Create an email to DL-HIMS-RESEARCH@stanfordchildrens.org
2. In the email message, please include:
 - a. Research Document type (consent form, lab result, etc.)
 - b. Participant name, MRN, and date of birth
 - c. Study name
 - d. PDF of document for upload
3. Encounter date to which document should be associated