



I. SCOPE

The SOP applies to all personnel who conduct or operationally support clinical research in Loyola University Medical Center (LUMC) and all research studies that have patient care services performed in LUMC facilities.

IMPORTANT: Timely association of the patient to the research study is critical to compliant research billing. If this SOP is not followed, the charges for any services performed in LUMC will be billed to the patient or his/her insurance without research review.

II. PROCEDURES

1. Study records are created in Epic as described in SOP PRO-011 Study Records in Epic. The study record must be Active for patients to be associated to the study.
2. There are nine enrollment statuses available in Epic. A patient may have one enrollment status at a time. The enrollment statuses are in 3 buckets:
 - a. Pre-Consent
 - (1) Interested – Patient is interested in the study and has yet to sign consent
 - (2) Waiting for Consent – Patient verbally gave consent to participate in the study but did not sign the consent document
 - b. Active
 - (1) Consented - In Screening – For studies with screening processes, patient signed the consent to participate in the study and is in the screening process.
 - (2) Enrolled – Patient signed the consent to participate in the study. For studies with screening processes, the patient completed screening and is eligible to participate in the study.
 - (3) Long Term Follow-Up – Patient entered the long term follow-up phase of the study.
 - c. Inactive
 - (1) Declined – Patient declined participation in the study.
 - (2) Completed – Patient completed participation in the study.
 - (3) Withdrawn – Patient withdrew consent to participate in the study.
 - (4) Screen Failed – Patient consented to participate in the study but was not eligible to continue participation.
3. Pre-Consent enrollment statuses may be used at the discretion of the Principal Investigator and/or his/her designee ("Study Team").
4. When a patient consents to participate in a study, the Study Team associates the patient to the study in Epic with an Active enrollment status (Consented- In Screening, Enrolled, or Long Term Follow Up).
 - a. Patients are to be associated at the time consent is obtained and no later than before the patient presents to the hospital/clinic for the first study-related patient care service.
 - b. This is required for studies that have patient care services performed for study purposes (studies with a coverage analysis or billing guidance document as described in SOP FIN-001 Coverage Analysis Development). It is optional for studies that do not have patient care services, such as registry studies.
 - c. The status may be whichever Active status is most appropriate in the opinion of the Study Team.



-
- d. The following additional information should be added as applicable:
 - (1) Start Date
 - (2) Patient Study ID
 - (3) Branch (arm)
 - (4) Study Coordinator(s)
 5. If applicable and/or once available, include the following information in the Notes section of the Research Studies screen to facilitate accurate charge routing:
 - a. Milestone dates (e.g. date of Visit 1 or Cycle 1 Day 1)
 - b. The sub-studies to which the patient consented
 6. While a patient has an Active enrollment status for a study that requires patient care services, all the patient's charges are routed for research charge review. LUMC Revenue Integrity reviews the patient's charges against the study's Coverage Analysis or Billing Guidance document, and the encounter linking as described in SOP PRO-013 Linking Encounters in Epic, and routes each charge to the patient's insurance or to the research study account.
 7. Once the patient's participation in the study is complete or the patient has reached the Deactivation Milestone stated in the study's Coverage Analysis, the Study Team updates the patient's enrollment status to an Inactive status (Declined, Completed, Withdrawn, or Screen Failed).
 - a. The patient's enrollment status is updated as soon as possible to avoid holding the patient's medical charges unnecessarily.
 - b. The status may be whichever Inactive status is most appropriate in the opinion of the Study Team.
 - c. The patient's enrollment status must be changed back to an Active status if the patient unexpectedly requires a research-related patient care service that is to be billed to the study.
 8. If at any time a patient care service to be paid for by a study is performed for a patient that did not have an Active enrollment status for that study at the time the service was performed, the Study Team must inform Revenue Integrity within 24 hours of the service. The study team provides the LU#, patient MRN, and date of service to request a manual bill hold on the patient's account.

For example, if the Study Team unexpectedly was unable to perform a venipuncture and the hospital lab was utilized, the Study Team must confirm the patient has an Active enrollment status for the study in Epic before the venipuncture is performed. If the patient does not have an Active enrollment status before the venipuncture is performed, the Study Team must inform Revenue Integrity.

III. ASSOCIATED DOCUMENTS AND FORMS

1. LUMC Epic Training Document Enroll & Manage Research Study Patients
2. SOP PRO-011 Study Records in Epic
3. SOP FIN-001 Coverage Analysis Development
4. SOP PRO-013 Linking Encounters in Epic



LOYOLA
UNIVERSITY
HEALTH SYSTEM



LOYOLA
UNIVERSITY
CHICAGO

Associating Patients
in Epic for Research Billing
PAT-002
Effective date: 01-APR-2019

IV. APPROVALS

Stephanie Ellis 3/4/19
LUMC Director, Revenue Integrity (or designee) Date

John Moore 2/22/2019
LUC Senior Director, Clinical Research Office (or designee) Date