



## I. SCOPE

This SOP applies to applicable patient care services to be provided in a Loyola University Medical Center (LUMC) that are to be billed to a research study.

Applicable patient care services include: office visits, all imaging (CT, MRI, ultrasound, etc), biopsies, drug infusions and injections, and surgical procedures. They do not include clinical laboratory tests, inpatient services, or observation.

If this procedure is not followed, the patient will be required to pay a co-pay or pre-pay when he/she presents to LUMC for service. Scheduled services may be cancelled if the patient's insurance denied the prior authorization request.

## II. PROCEDURES

- A. The Principal Investigator or his/her designee ("Study Team") are to be aware of the anticipated payer for patient care services performed in support of each clinical research study as specified in the Coverage Analysis document.
- B. If an applicable patient care service is scheduled for a research participant and it will be billed to the research study, the Study Team adds an FYI Flag in the patient's record.
- C. To add an FYI Flag, the Study Team:
  1. Logs into Epic.
  2. Opens the research participant's chart.
  3. Clicks on 'FYI'.
  4. Clicks New Flag and selects Reg to Reg Communication.
  5. Enters the following in the text field: "RESEARCH-PAID [*name of service*] on [*date of service* MM-DD-YYYY]. Do not collect a co-pay or pre-pay for this service; do not financially secure this service; and do not cancel this service due to lack of insurance coverage. This service will be billed to a research study, not to the patient or to insurance."
  6. Saves the FYI Flag.
- D. This should be completed as soon as possible after scheduling.
  1. The Financial Clearance Center contacts the patient's insurance for prior authorization soon after the service/procedure is scheduled, typically 1-2 weeks before the service is performed. If the FYI Flag is not available at the time Financial Clearance works the account, the patient's insurance will be contacted and the service/procedure may be cancelled if insurance denies coverage.
  2. At a minimum, the FYI Flag should be entered 24 hours before the service is to be performed.
- E. In addition to the FYI Flag, the Study Team may document a service is to be paid for by the study in the appointment or order notes.
- F. Before initiating co-pay, pre-pay or securing activities, LUMC Service Representatives and Financial Clearance team:
  1. Check to see if the patient is associated with a research study in Epic.
  2. If the patient is associated with a study, check the Reg to Reg Communication FYI flags for a research communication as described above.
  3. If a research communication applies to the service of interest, the colleague follows the guidance in the communication and does not collect a pre-pay/co-pay or secure the account.
- G. After the encounter, the Study Team deactivates the FYI Flag.

## III. REFERENCES

- A. SOP FIN-001 Coverage analysis development



B. SOP PAT-002 Associating patients in Epic for research billing

IV. ASSOCIATED DOCUMENTS AND FORMS

A. Guidance Document: Notifying Financial Clearance and Service Representatives that a service will be paid for by a research study

V. APPROVALS

[Signature] 8/6/2018
LUMC EVP, Clinical Affairs (or designee) Date

[Signature] 7/27/18
LUC Senior Director, Clinical Research Office (or designee) Date