



## I. SCOPE

The purpose of this SOP is to provide a standardized approach for Financial Clearance Center (FCC) colleagues who are obtaining prior authorization for a service for a patient who is enrolled in a research study.

Prior to a study's initiation, LUMC Clinical Research (LUMC CR), LUMC Revenue Integrity, and the study team finalize a coverage analysis on all study-related patient care items and services. A coverage analysis is the industry best practice for assessing which patient care items or services are routine costs (also referred to as standard of care) and which are solely for research purposes. [See research SOP FIN-001 Coverage Analysis Development.] Routine costs are billed to the patient or the patient's insurance. Items and services that are not justifiable as routine costs are billed to the research study. They are not billed to the patient or the patient's insurance.

Transplant financial counselors are responsible for obtaining prior authorizations for transplants. Transplant financial counselors may utilize this work flow if applicable for a transplant.

## II. PROCEDURES

- A. For FCC colleagues, when working an account, assess if the patient is currently enrolled in a research study in Epic by:
  1. Checking the patient's header for Research: Active indicator
  2. Checking Patient Care> Research
- B. If the patient is enrolled in a study, assess if the item or service to be authorized is paid for by the research study by reviewing the patient's Reg-Reg FYI Flags. [See research SOP PAT-003 Communication of Research-Paid Patient Care Service.]
  1. If the item or service is to be paid for by the study, do not seek authorization. Remove the account from the WQ.
  2. If there is no FYI Flag but it appears the item may be paid for by the research study, contact Revenue Integrity's Research Billing team or LUMC CR for confirmation.
  3. If the item or service is not noted as paid for by the study and/or was confirmed not to be paid for by the study, it was prospectively determined to be a routine cost and is to be billed to the patient or the patient's insurance.
- C. FCC colleagues should obtain authorization for the service through their normal process with the following exceptions:
  1. Provide the payer with the Routine Costs in Research cover letter.
  2. For studies that involve investigational devices, many device manufacturers offer assistance in securing authorizations. LUMC CR will provide the manufacturer's documentation and contact information if requested.
  3. If the payer denies the prior authorization based on clinical trial participation or requests additional information about the study, provide the following study information:
    - a. Clinicaltrials.gov number
    - b. Coverage Analysis
    - c. Consent FormThis information may be provided by LUMC CR or the study team.
- D. If the payer denies the prior authorization again, the FCC colleague sends an Epic InBasket notification to the treating physician that a peer to peer review is needed.
  1. The treating physician informs Revenue Integrity and LUMC CR about the denial. Revenue Integrity and LUMC CR are available to provide support in responding to the denial as requested by the treating physician and as permitted by the payer.
  2. It is recommended a representative from Revenue Integrity or LUMC CR be present on any phone call with the payer.



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- E. If a study is expected to enroll greater than 20 participants, the study team and LUMC CR prepare a packet with information about the study's routine costs to be sent to LUMC's top two payers (not including CMS) at the time of study initiation.

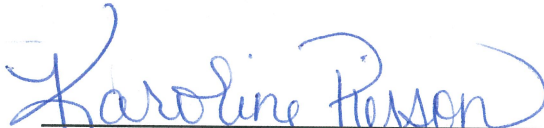
**III. REFERENCES**


- A. Research SOP PAT-003 Communication of Research-Paid Patient Care Service
- B. Research SOP FIN-001 Coverage Analysis Development
- C. Medicare NCD 310.1
- D. Illinois General Assembly Insurance Code 215 ILCS 5/364.01

**IV. ASSOCIATED DOCUMENTS AND FORMS**

- A. Routine Costs in Research cover letter

**V. APPROVALS**

  
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Director, Financial Clearance Center

  
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Date