I. SCOPE

The SOP applies to research studies that will have patient care services performed in LUMC facilities.

II. PROCEDURES

1. Activation
   a. The first week of each month, LUC HSD Informatics creates an export file from the Research Channel that includes human subjects' research studies approved by the IRB the previous month.

   b. LUC HSD Informatics FTPs the file to the Epic FTP server.

   c. The LUMC Epic Analyst removes duplicate entries then imports the file into Epic. Each entry creates a new research study administrative (RSH) record with the following information:
      (1) Study ID: LU
      (2) Study name: short study title
      (3) Description: protocol title
      (4) IRB approval: IRB approval date
      (5) Billing status: Inactive
      (6) NCT: NCT
      (7) Billing contact person: study contact
      (8) Principal Investigator: principal investigator (providers only)
      (9) Service Area: LUMC
      (10) Guarantor type: Research

   d. At the time of LUMC Institutional Approval, LUMC Clinical Research (LUMC CR) updates the RSH record with the following information:
      (1) Study Type:
         (a) Interventional: qualifying clinical trial or study with research-paid patient care services (requires research billing review)
         (b) Investigational Device Study: clinical trial conducted under an IDE
         (c) Observational: study with no research-related patient care services
         (d) Interventional - Non-Qualifying: a non-qualifying clinical trial or study with no research-paid patient care services
         (e) Expanded Access: expanded access protocol that is not research
         (f) Coverage with Evidence Development: protocol that is not research but for which research coding is required because it is a CMS-approved CED
         (g) Non-Research: record is not related to research or research billing, e.g. a client record
      (2) Billing contact person: update to reflect the budget administrator, email, and zip code
      (3) Study Coordinators as listed in the IRB application
      (4) Link to the study's clinicaltrials.gov webpage
      (5) Study branches for studies with more than one arm
      (6) Automated actions as requested by the study team
      (7) HB fee schedule and adjustment posting
      (8) PB pricing contract
      (9) Report Grouper Category 5 with funding type

   e. LUMC CR changes the record's billing status to 'Active'.

   f. LUMC CR informs the study team the study is active in Epic.

g. If the Study Team identifies a study is not in Epic :

(1) The Study Team emails LUMC Clinical Research ("LUMC CR") with the LU, study short title, and the MRN and date of consent for patients consented to the study. If LUMC CR is not staffed that day, the Revenue Integrity's Research Billing Team is also contacted.

(2) LUMC CR requests LUMC Revenue Integrity manually place stop bills on encounters that may be impacted by the delay in each patient's study association in Epic.

(3) LUMC CR confirms the study has IRB approval and LUMC Institutional Approval.
(a) If a patient was consented to the study before IRB approval was obtained, LUMC CR informs the IRB and the director/manager of the applicable Study Team immediately.
(b) If a patient was consented to the study before LUMC Institutional Approval was obtained, LUMC CR will determine if study activities need to be placed on hold until Approval is obtained.

(4) Once LUMC CR confirms the study has IRB approval and LUMC Insitutional Approval, LUMC CR activates the RSH record for the study and notifies the study team.
(5) LUMC CR informs Revenue Integrity once confirmation of successful study association is received.

2. Inactivation
a. The study team notifies LUMC CR when all patient activity is complete for the study.
b. LUMC CR informs Revenue Integrity.
c. Once the account is settled, Revenue Integrity informs LUMC CR.
d. LUMC CR inactives the RSH record once it is confirmed no further patient activity is to occur and the accounts are settled.

III. ASSOCIATED DOCUMENTS AND FORMS

A. PAT-002 Associating Patients in Epic for Research Billing
B. PRO-003 LUMC Operational and Financial Assessment of Research
C. LUMC Administrative Policy: Institutional Approval of Clinical Research

IV. APPROVALS

LUMC EVP, Clinical Affairs (or designee) — Date 1/25/19

LUC Senior Director, Clinical Research Office (or designee) — Date 1/14/19