Baylor St. Luke's Medical Center

# Guide to Conducting Clinical Research at Baylor St. Luke's Medical Center

Baylor St. Luke's Medical Center

# Office of Clinical Research

# Research Administration Office

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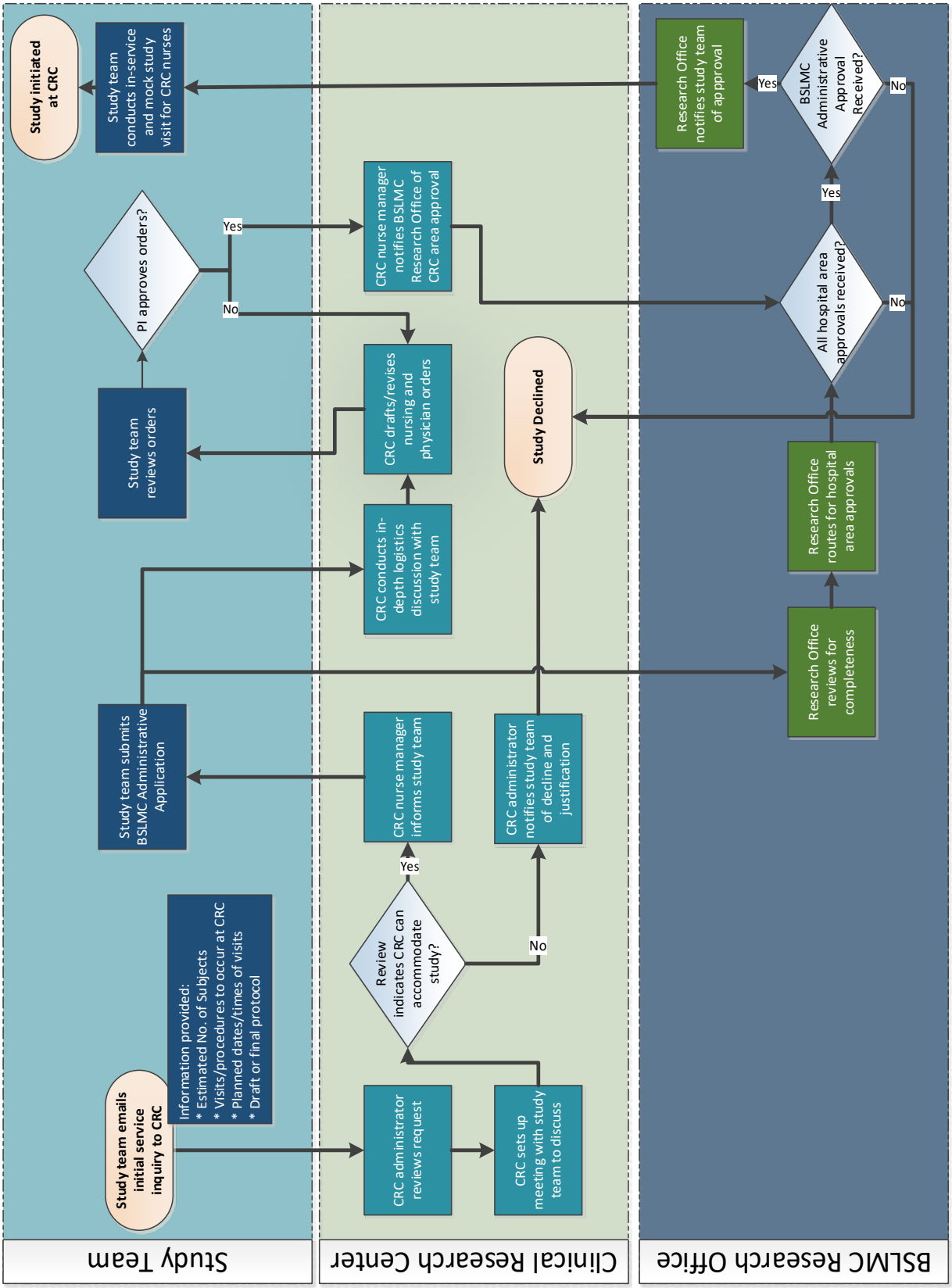

Baylor St. Luke's Medical Center

# Introduction to Clinical Research at Baylor St. Luke's Medical Center

Baylor St. Luke's Medical Center (BSLMC) is home to world-class clinical care and supports top-tier clinical research through its collaborations with academic and private practice investigators. The purpose of this guide is to provide research staff with an overview of services, procedures, and requirements for conducting clinical research at BSLMC.

## *Principal Investigator Responsibilities*

Prior to enrolling participants in any research project conducted at BSLMC, it is the responsibility of the Principal Investigator to obtain both:

(1) IRB approval from a BSLMC-accepted IRB, and

(2) Administrative approval from the BSLMC Research Office, and/or

(3) Review and approval from CommonSpirit Health Research Institute (CSHRI)

BSLMC uses an administrative review and approval process to assist with oversight and management of research in BSLMC facilities. Before beginning any research at BSLMC, Principal Investigators must first obtain administrative approval. Approval requires submission of a completed Administrative Application, which is reviewed by all BSLMC areas directly impacted by the study as well as executive leadership. The administrative approval process includes a review of each protocol to ensure patient safety, operational and financial feasibility and hospital compliance.

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# The BSLMC Administrative Approval Process

## *Initiation*

To initiate the BSLMC administrative review and approval process, Investigators must submit a BSLMC Administrative Application.

Application requirements include submission of study documents. You may give BSLMC Research Office view-only access to your IRB submission as shown in *Appendix I*, or you may attach the documents to your Administrative Application.

See Submitter/PI Guide in *Appendix II*.

Supplemental forms are required if your study includes investigational device purchase, research pricing, access to PHI without subject authorization, or the Clinical Research Center. More information on this is below. Sample forms are available in *Appendix II*. Contact the BSLMC Research Office (713-798-6024; BSLMC_Research@bcm.edu) with questions.

Upon submission of the Administrative Application, the BSLMC Research Office initiates the review and approval process.

## *Review*

The BSLMC Research Office conducts administrative review of the application, which includes:

- Verifying IRB approval
- Verifying CITI training for research personnel identified on the IRB application. Current training requirements are described on the administrative application.
- Verifying BSLMC credentialing for the principal investigator (see *Badging and Credentialing*, below).
- Providing research pricing and executing a fee schedule for research procedures conducted at BSLMC. See next section, *Research Pricing and Fee Schedules*, for more information.
- Obtaining approval from hospital areas affected by the study, as indicated in the Administrative Application.
- Obtaining approval from any BSLMC special committees that may apply (i.e. Radiation Safety).
- Routing drug studies to the BSLMC research pharmacy for review.
- For device studies, routing device purchase agreements and related documents for BSLMC review, verifying CMS coverage and obtaining charge codes. See *Device Study Impact Analysis* for more information on this process.
- Ensuring study teams conduct in-services for BSLMC staff in areas utilized by the study. See *Patient Care In-Services*.
- Conducting a CommonSpirit Health compliance review to ensure compliance with HIPAA authorization requirements and conflict of interest disclosure and verify regulatory committee approvals and compliance with CSH national policies. See *Appendix III* for sample review template and description.

## *Approval*

The Research Office works with the Principal Investigator and study team to clarify any logistical, financial or regulatory issues. Following completion of administrative review, the Research Office routes the application for BSLMC executive review. The BSLMC Research Office will notify study teams of approval/disapproval.

## *After Approval*

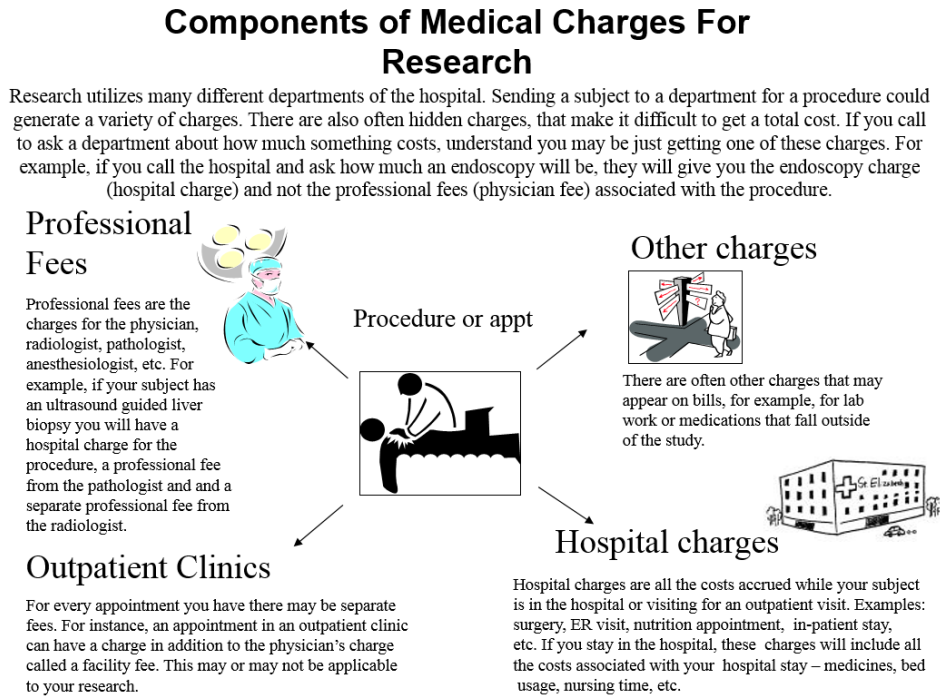
Once a study receives administrative approval, the BSLMC Research Office creates a study-specific record in Epic if applicable. This record is associated with patient encounters to allow billing to the study account. See *Appendix VII* for details of information entered into the Epic study record.

In addition, the BSLMC Research Office adds the approved study to the BSLMC public clinical study recruitment website. The searchable website is accessible to the public through the BSLMC research website and serves as a recruitment aid for trials conducted at BSLMC.

Renewal of administrative approval is not required. However, study teams should notify the BSLMC Research Office of changes that may impact BSLMC. This includes changes in study status, modifications to visit procedures that may affect billing, and principal investigator changes.

Reference: BSLMC Policy & Procedure, *Protocol Administrative Review*.

## *Research Pricing and Financial Agreement*




BSLMC provides discounted hospital pricing for research procedures and tests. The BSLMC Research Office coordinates with BSLMC Finance to obtain a study-specific research pricing based on the schedule of events

provided by the study team in the Administrative Application. Study teams may contact the BSLMC Research Office at any time for assistance with BSLMC pricing for study feasibility or budget preparation purposes.

To ensure complete and accurate pricing, the study schedule of events submitted with the administrative application must clearly delineate each procedure as billable as conventional care or research and include CPT and ICD-10 codes for outpatient and inpatient procedures, as applicable. Approved pricing is integrated into a study-specific fee schedule that requires principal investigator signature. The fee schedule itemizes the research pricing for any protocol-required tests/items covered by the sponsor. See example Fee Schedule in *Appendix II*.

Although not required for administrative approval, study teams are responsible for completing the Medicare-required Qualifying Clinical Trial coverage analysis before study initiation and providing upon request to the BSLMC Research Office.

Please note: Professional fees are supplied by outside providers and their fees are billed separately from the hospital charges. The BSLMC Research Office can provide the study team with some contact information for research price negotiations with hospital-contracted professional providers.

BSLMC Patient Financial Services utilizes the pricing provided in the Financial Agreement to create research invoices. See *Research Charge Routing and Review*, below, for more information on this process.

Reference: BSLMC Policy & Procedure, *Billing Compliance - Research*

## *Ethical and Religious Directives*

Ethical and Religious Directives (ERD) guide healthcare conduct at BSLMC. The Research Office has a policy regarding ERD requirements while supporting research at BSLMC. The Research Office includes review of consent forms for ERD in the compliance review.

## *Patient Care Area In-Services*

BSLMC staff directly involved in study conduct must be informed and/or trained in the study purpose and procedures. During the administrative review process, the BSLMC Research Office will provide the study team with a list of units where in-service is required. The study cannot begin until all appropriate in-services have taken place.

## *Request for Access to PHI for Research Purposes without Patient Authorization*

Individuals engaged in research at BSLMC who wish to access Protected Health Information (PHI) for research or feasibility purposes without a patient's authorization must document the access by completing the *Request for Access to Protected Health Information for a Research Purpose without Subject's Authorization* form (see sample in *Appendix II*).

This includes studies where the requirement for subject authorization has been waived by the IRB or decedents only are being accessed, or the information gathered will be preparatory to research.

Researchers must complete and maintain a copy of the request form for each study or access request. A copy of the form must also be provided to the office providing access (such as Health Information Management), as applicable.

## *Research Credentialing for Badging and Epic*

Non-clinical, non-BSLMC employees who are involved with any research study at BSLMC must complete the following steps to obtain site access, EPIC & other IT system accesses, and an issuance of a BSLMC badge. Additional information can be found on the BSLMC research website: https://www.stlukeshealth.org/locations/baylor-st-lukes-medical-center/research/conducting-research-baylor-st-lukes-medical-center

- Initial Application:
  - Submit the following documents to the BSLMC Research Office:
    - BSLMC Research Credentialing Initiation Questionnaire
    - TB Symptom Review Form
    - Immunization Records
    - Negative Drug Screen
- Renewal:
  - Once approved, your BSLMC non-employee contract will be valid for one year. It is your responsibility to renew. Watch for notifications from the HR system in advance of contract expiration and submit the following prior to expiration for renewal to BSLMC Research Office (bslmc_research@bcm.edu).
    - Immunization Records
    - Proof of annual influenza vaccination
    - Proof of annual TB testing
    - Badge request form (if applicable)
    - Email BSLMC Research Office if your BSLMC Epic or other BSLMC IT accesses need to be renewed at this time.

Conditions of Badging:

- External Research Personnel must complete human subject's protection training through CITI (Biomedical Research and HIPAA).
- External Research Personnel are required to introduce him/herself to hospital area manager upon receiving access to a hospital unit.
- External Research Personnel are required to follow all applicable BSLMC Policies & Procedures. Failure to do so may result in loss of privileges.

## *Research Pharmacy*

BSLMC Pharmacy Research Services supports research drug and biologic dispensations for studies conducted at BSLMC. Pharmacy Research Services is compliant with the Texas Board of Pharmacy regulations, United States Pharmacopeia (USP) Chapter 797 pharmaceutical sterile compounding regulations and with state, federal and CHI Institutional Review Board regulations for the conduct of

research. BSLMC requires that all investigational product entering BSLMC facilities be dispensed through the BSLMC Research Pharmacy. Study teams wishing to utilize pharmacy services should indicate requirements on the administrative application and provide applicable study documents, such as investigator's brochure or pharmacy dispensing protocol. The pharmacy will contact the study team regarding study needs and create an agreement describing pharmacy services and pricing for the study.

Location:
Baylor St. Luke's Medical Center
Pharmacy Department, Room Y404
6720 Bertner Avenue
Houston, TX 77030

Contact:
Punit M. Hinsu, PharmD, MBA, MPH
Clinical Pharmacist II
Research & Investigational Drug Service

Office: 832.355.4893
Fax: 832.355.4794
Pager: 713.605.8989 Pin #25403
Email: phinsu@stlukeshealth.org

## *Pathology*

The BSLMC Pathology Department is an active participant in the hospital's administrative review process for research protocols. All hospital-based tests and/or tissue collection needs should be outlined in the Administrative Application.

Location:
Baylor St. Luke's Medical Center
1st floor, Room P120 (by purple elevators)
6720 Bertner Avenue
Houston, TX 77030

### *Laboratory Tests*

Clinically indicated and research-specific laboratory tests associated with an IRB-approved research protocol may be sent to the Pathology laboratory for testing if the test is offered on the laboratory test menu. Tests performed on-site are discounted for research purposes. Tests sent to other labs by the BSLMC lab cannot be discounted. Prices are subject to change annually.

### *Tissue Collection*

Tissue collection procedures at BSLMC must be reviewed and approved by BSLMC Pathology before collection can occur. Tissue samples for research are only to be collected under IRB approved protocols and only after receiving BSLMC administrative approval. Study teams shall submit the tissue collection information on the BSLMC administrative application. BSLMC Pathology will review the study information and work with the study team on specific processing based on study needs.

When a research participant is scheduled for a procedure that involves research tissue procurement, the study team shall inform Pathology in advance via email and submit an Epic requisition for the collection. Pathology shall review the requisition and contact the study team with any questions. Tissue shall be collected, processed, and dispensed in the manner approved by Pathology. The principal investigator is responsible for coordinating collection between the clinical team, study team, and Pathology.

Tissue will not be collected without a signed informed consent on file. The informed consent should be attached to the Epic requisition and/or sent to Pathology before collection occurs. Tissue may not be collected outside of the approved collection process without prior notification and approval of Pathology.

Reference: BSLMC Policy & Procedure *Research Tissue Collection Process.*

# Research Visits

## *Scheduling research visits at BSLMC*

Research visits at BSLMC are scheduled through BSLMC Patient Access Services' call center. Study-specific information is required to ensure the visit encounter is correctly entered into Epic. The steps for research visit scheduling are as follows:

1. Complete the BSLMC Call Center/Registration Research Form (see sample in Appendix II) by filling in the IRB #, the ordering physician name, diagnosis, research coordinator name and contact number, fax or email for confirmation of scheduling information. Research patient visits should be scheduled at least two business days in advance when possible.
    a. In the comments section you may request a date for the test or any other specifics.
    b. The Research Registration form is available on the BSLMC Research website
2. Prepare Physician's Orders for visit. The physician order must contain:
    a. Date/Time
    b. Diagnosis
    c. Specific test order
    d. Any special instructions for the test
    e. Physician signature
3. Fax the registration form, Physician's orders, and signed research informed consent form (ICF) (if available) to the number indicated on the form.
    a. BSLMC will attach the consent to the patient's medical record. This step is required for hospital compliance purposes and research identification. If the ICF is not available at the time of scheduling, the study team is responsible for ensuring it is forwarded for association as soon as available. Please refer to the section, *Associating Patient Records with Informed Consents* (below) for specific details.
4. Patient Access Services will verify insurance and contact the patient to schedule the visit.
5. Patient Access Services will create a medical record number (MRN) and Hospital Account Record (HAR) if none exists for the patient. A new HAR is created for each visit.
6. Patient Access Services will then contact the research coordinator indicated on the form to confirm date and time of visit.

7. Once the visit has been confirmed by Patient Access Services, the patient's medical record and HAR must be associated with the study-specific research record in Epic. Study personnel with Epic access may complete this task or notify the BSLMC Research Office to make the association. Please see the next section, *Associating Patient Records and Linking Visit Encounters to Epic Research Records* (below) for specific details.

## *Scheduling Research Subjects in the Operating Room (OR)*

To ensure all research subjects scheduled in the OR are identified, prepared, and managed according to study protocols and institutional policy.

1. Initial requirements:
    a. Obtain BSLMC administrative approval for the research project.
    b. Conduct an in-service training for OR staff, ensuring they are informed of study protocols, patient handling, and documentation requirements.
2. Steps to scheduling and communicating research procedure in OR
    a. Flag Research Patient in Epic
    b. Upload the signed research consent form to the patient's EMR.
        i. Refer to the BSLMC approval letter for the timeline requirement on uploading consent documents, as this must align with hospital and study guidelines.
    c. Place Orders for Procedure and Required Tests:
        i. Enter the order for the procedure and any related tests in Epic.
        ii. Associate each order with the correct research diagnosis code (Z00.6) and study protocol to ensure procedural accuracy and proper billing.
    d. Schedule Patient via the Applicable OR Department:
        i. Coordinate with the OR scheduling team to reserve an OR slot that accommodates study requirements.
        ii. Provide the OR department with necessary patient and procedural information, ensuring transparency on any special needs or timing requirements.
    e. Communicate with OR Team:
        i. The study team should notify the OR staff and any relevant departments about the scheduled research procedure.
        ii. Confirm that all team members are aware of the research-specific requirements and have access to the patient's flagged record and consent in Epic.
    f. Study Coordinator Presence during procedure:
        i. The study coordinator must be present or on standby during the entire procedure to:
            1. Coordinate any research-specific aspects of the procedure.
            2. Answer questions from the OR team and address any unexpected study-related requirements.
            3. Ensure the study is conducted in compliance with the approved protocol

By following this guide, the research and OR teams can collaborate effectively to provide safe, compliant care for research subjects undergoing OR procedures. This structured approach supports both patient care and adherence to research protocols from scheduling through completion.

For questions, contact BSLMC Research Office via email at BSLMC_Research@bcm.edu, 713-798-6024

## *Associating Patient Records and Linking Visit Encounters to Epic Research Records*

Association of patient records and linkage of research encounters (visits) to study-specific research records in Epic are required to ensure research billing compliance. Study teams must notify the BSLMC Research Office of research encounters prior to the date of the encounter. BSLMC Research Office will verify the patient record is associated to the research record and the encounter is linked appropriately in Epic. Failure to associate patients and encounters with the research record will result in charges automatically routing for standard clinical billing to patients and/or their insurance.

Reference: BSLMC Policy & Procedure, *Billing Compliance - Research*

### *For study teams without Epic access*

The study team must notify the BSLMC Research Office via email prior to or on the date of the visit using the following template. Please note this information must be sent in a secure fashion.

Email to: BSLMCPatientNotifications@bcm.edu

Subject line: [secure] Research Patient Notification

| | |
|---|---|
| Patient Name: | |
| Patient DOB: | |
| BSLMC MRN: | |
| Study Name: | |
| IRB #: | |
| IDE #: | |
| Enrolling Physician: | |
| Date of Consent: | |
| Date of study-related encounter: | |
| Study-related tests/procedures on this encounter: | |
| Additional information: | |

### *For study teams with Epic access*

Study teams with Epic access can associate the patient to the research study account and link the encounter for study procedures/tests using the below procedure. However, study teams must also notify the BSLMC Research Office of the association, as described in the above section.

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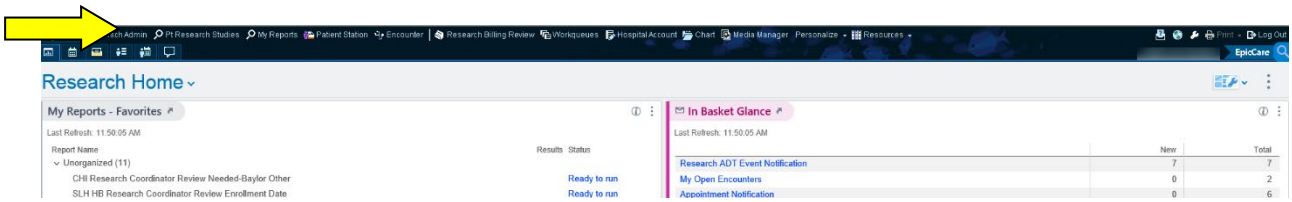
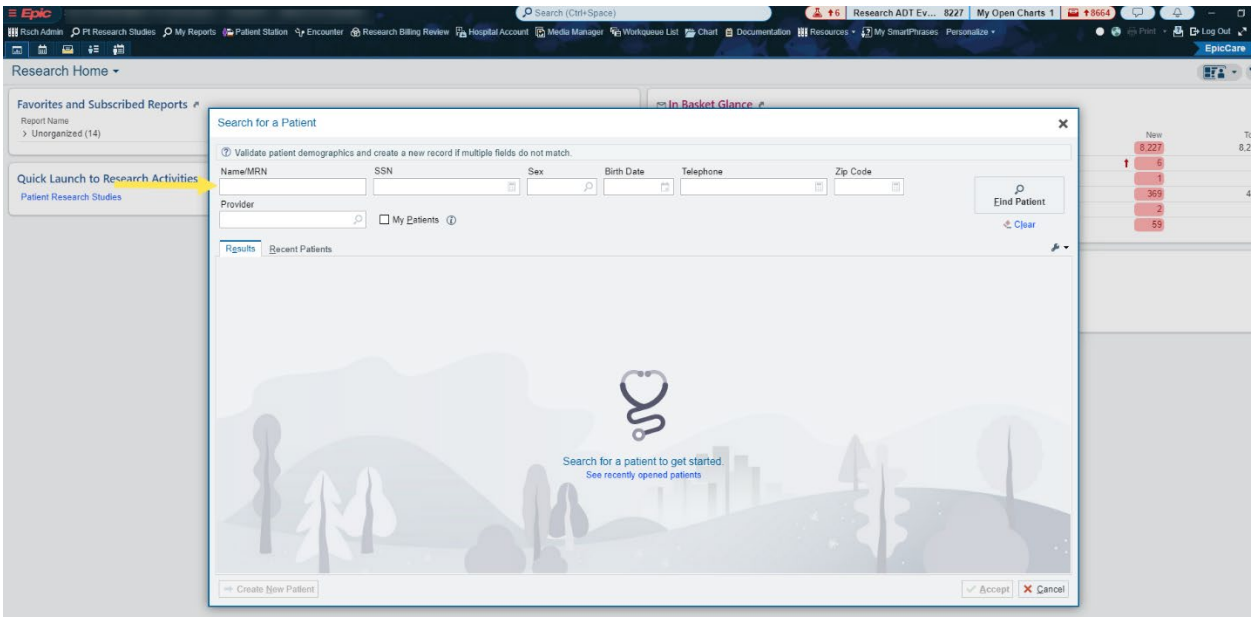
*To associate a patient record to a study in Epic*

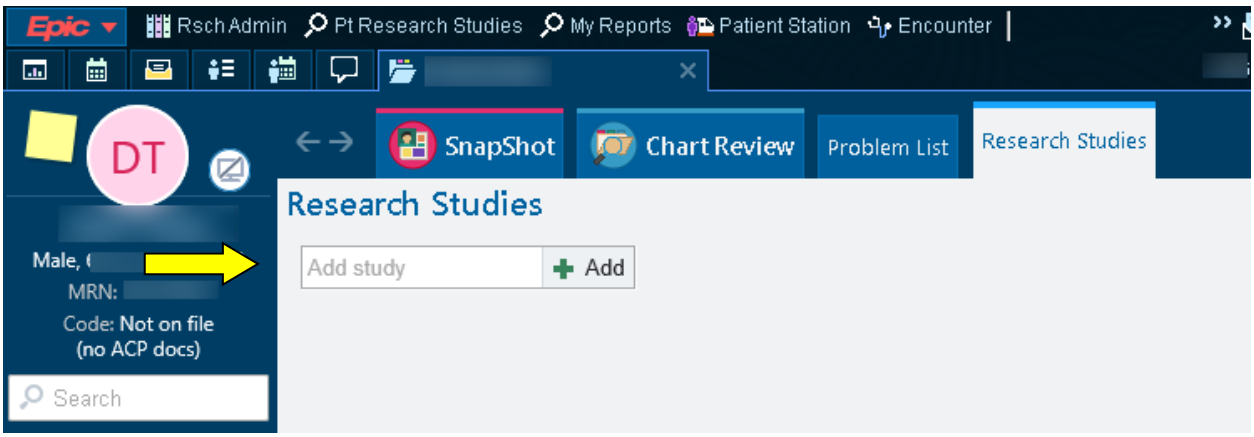
Step 1: Click on the "**Pt Research Studies**" button:




Step 2: Enter the patient's name, MRN, or SSN and click on "**Find Patient**":

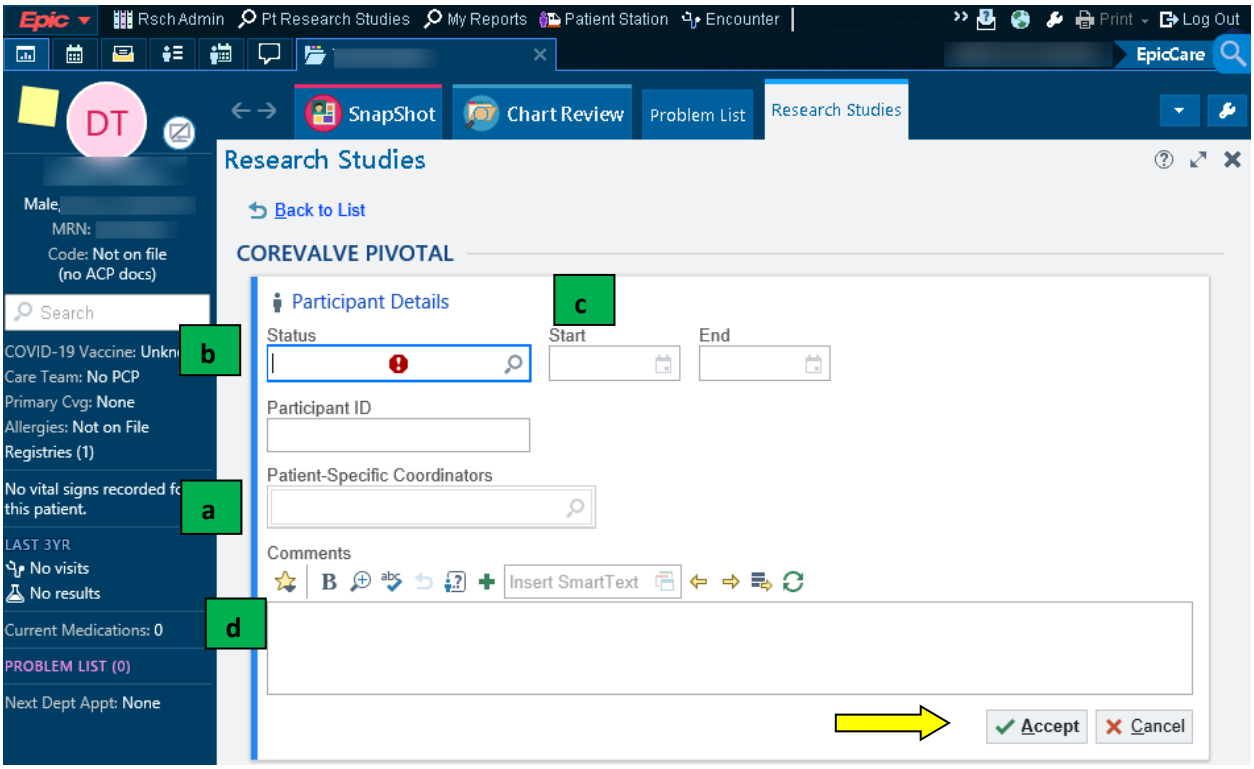



Step 3: Enter the IRB number for the study in the box provided and click "**Add**" OR click the "**Add**" button to search for the study:



Step 4: Enter the following information and click "**Accept**":

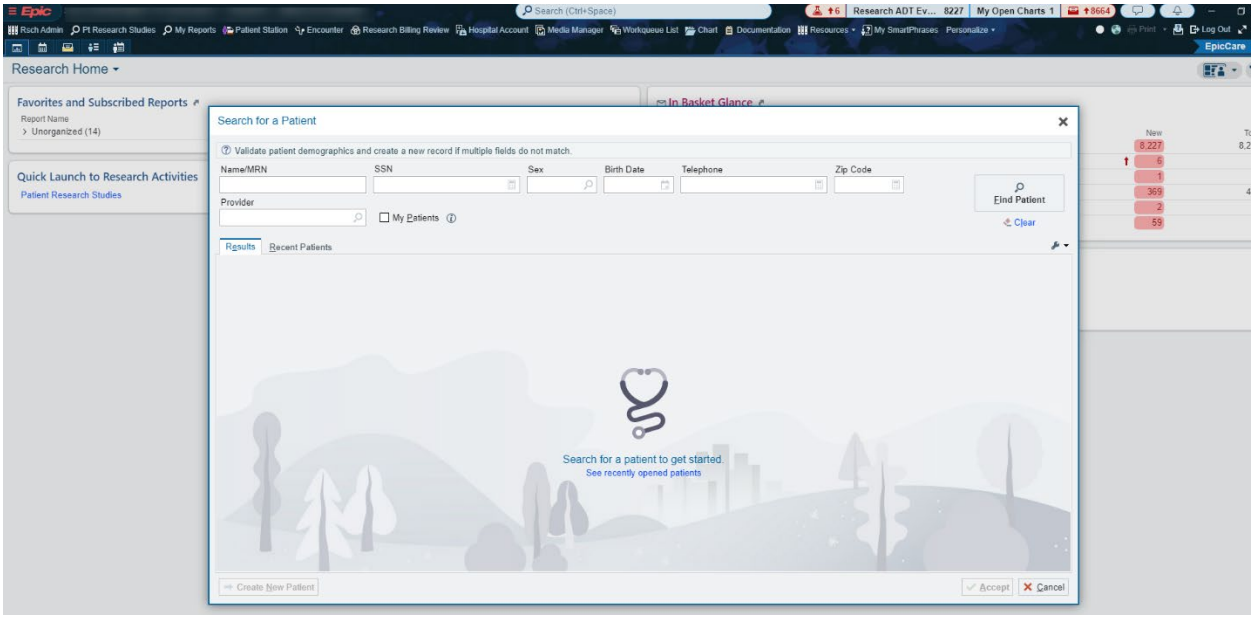
a. Coordinators (only Epic users can be entered in these fields)
b. Status: Several options available when the magnifying glass icon is clicked (Enrolled, Ineligible, Completed, etc.)
c. Active Start Date: Date the Research Informed Consent Form (ICF) was signed
    i. **NOTE**: If a patient signs the ICF while admitted in the hospital and the ICF date is *after* the admission date, the admission date must be entered as the Active Start Date. For all other patients, the actual ICF date should be entered as the Active Start Date.
d. Comments: Free text field can be utilized to add research notes or to document the informed consent process



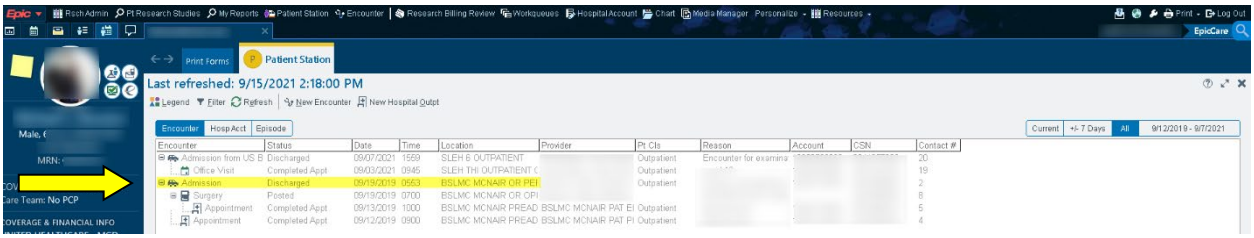

The patient's record is now associated with the study.

## *To link a specific encounter (visit) to the study in Epic*

Step 1: Click on the "**Patient Station**" button. The "**Patient Lookup**" box will appear: Enter the patient's name, MRN, or SSN and click on "**Find Patient**":

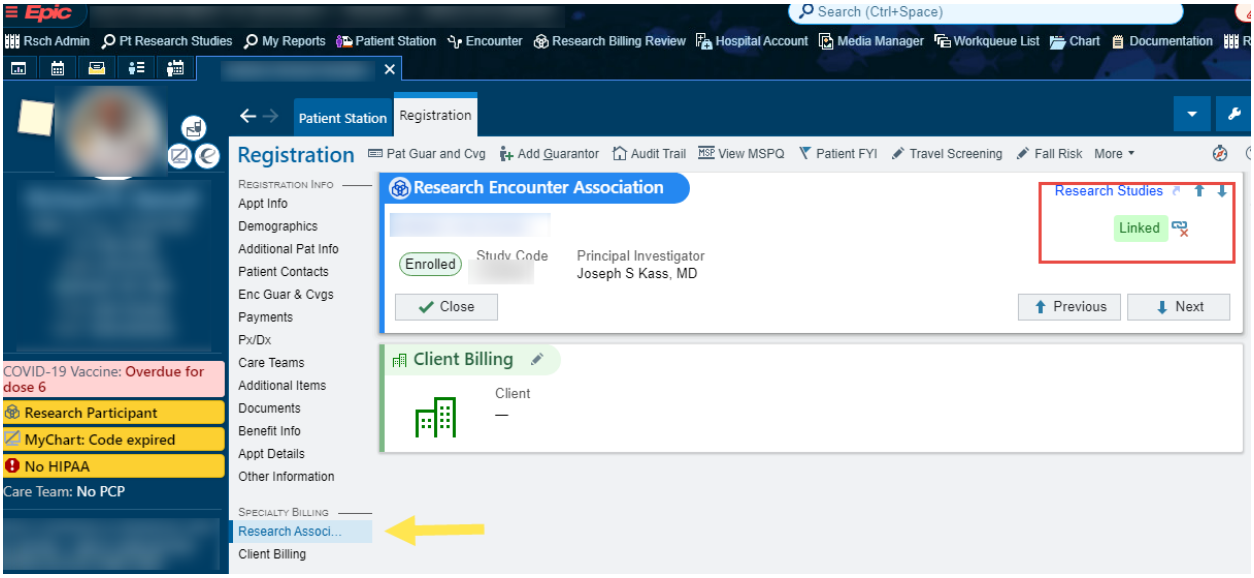



Step 2: Double click on the research related encounter (visit):



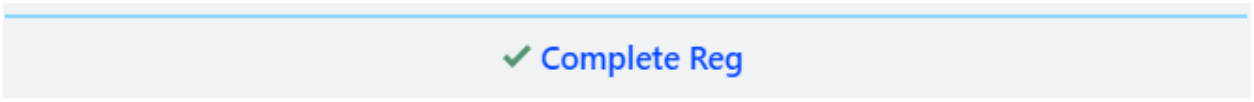
Step 3: Click on "**Research Association**":

Here you can link or unlink an encounter to the research study.




Step 4: Click on "**Complete Reg**":

After encounter has been linked, click on Complete Reg at bottom right of the page.




The encounter is now linked with the study.

## *Responsibility for maintaining current research patient status in Epic*

Study teams are responsible for maintaining current research patient status in Epic. Statuses include Identified; Interested; Ineligible – did not meet full criteria; Declined; Waiting for consent; Enrolled; Completed; Disqualified; and Withdrawn.

Study teams with Epic access may make this change directly in Epic. Study teams without Epic access must notify BSLMC Research Office when a patient goes off study by secure emailing BSLMCPatientNotifications@bcm.edu with the patient's name, medical record number or date of birth, IRB# and off-study status (Completed, Disqualified, Withdrawn).

Reference: BSLMC Policy & Procedure, *Billing Compliance - Research*

## *Associating Patient Records with Research Informed Consent Forms*

Baylor St. Luke's Medical Center requires that signed research informed consent forms are associated with research patients' electronic medical records for all studies utilizing informed consent. The BSLMC Research Office conducts monthly reviews of all research encounters and will notify study teams of missing research informed consent forms.

If the patient is consented outside BSLMC, study teams should fax the signed research informed consent form along with the call center registration form when scheduling the patient's BSLMC visit (see *Scheduling Research Visits at BSLMC*, above). The Call Center will associate the research informed consent form with the patient's medical record.

If the patient is consented at BSLMC, a copy of the signed research informed consent form should be sent to BSLMC Health Information as soon as feasibly possible. The signed research informed consent form can be placed on the patient chart by the study team, and it will be scanned into Epic for association with the patient's medical record within 48 hours of discharge.

Alternately, consents can be delivered to BSLMC Health Information Management office (6720 Bertner Ave., Room G-153) attention of HIM Request Desk Supervisor/HIM Request Desk. They can also be emailed to Crystalyn Jones crystalyn.jones@coniferhealth.com; Monica Perez monica.perez@coniferhealth.com; Thipprapa Thippayasri Thipprapa.Thippayasri@coniferhealth.com; and Yvonne Lopez yvonne.lopez@coniferhealth.com with Research Consent as the email subject line or faxed to 832-355-2661. When faxing the consent forms, please include a cover page with your contact information and include the patient name, date of birth, date of service and BSLMC MRN if known so that HIM can contact you if they cannot readily identify patient on consent form. Inter-office mail should not be used.
The informed consent should list the patient name, date of birth, date of service, and patient MRN or CSN. HIM will scan the informed consent into ChartMaxx, which makes the content available in the Epic media tab. Informed consents are typically scanned within 48 hours.

Reference: BSLMC Policy & Procedure, *Associating Patient Records with Informed Consents - Research*

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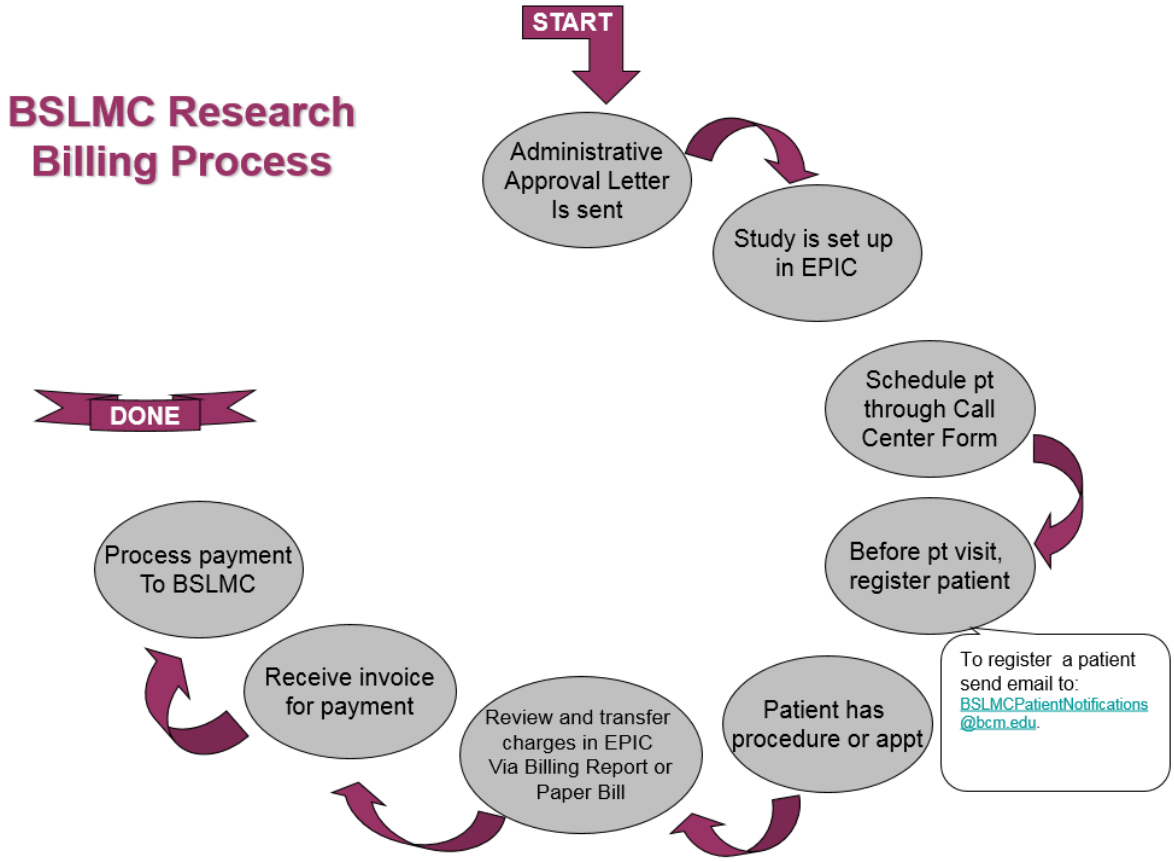
# Research Charge Routing and Review




## *Visit charge assignment*

Following each study visit, the study team is required to assign visit charges as either standard of care and billable to the patient/insurance or as research and billable to the study account. Charge assignment must be completed within two business days of receipt of the billing report/paper bill. The process for this varies based on Epic access.

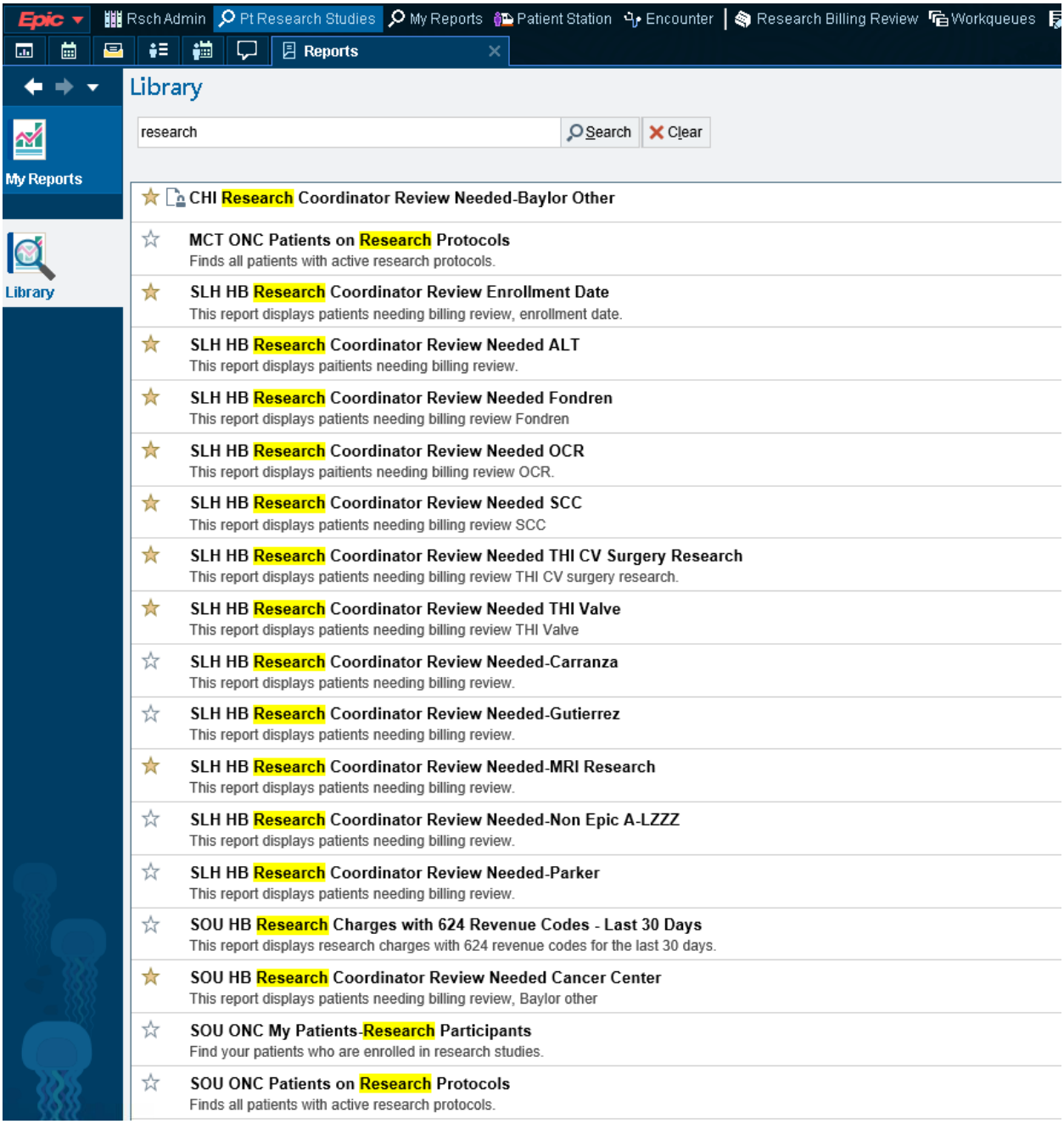
Research coordinators with Epic access can review charges for research patient visits on the Research Billing Review report, five days after closure of the encounter, transferring research items from the patient account to the study account, as shown below.

Coordinators without Epic access must review patient accounts on a clinical form and paper bill sent by Patient Financial Services, identifying which items on the bill are research and returning the itemized list to Patient Financial Services for transfer to the research study account, as shown below.

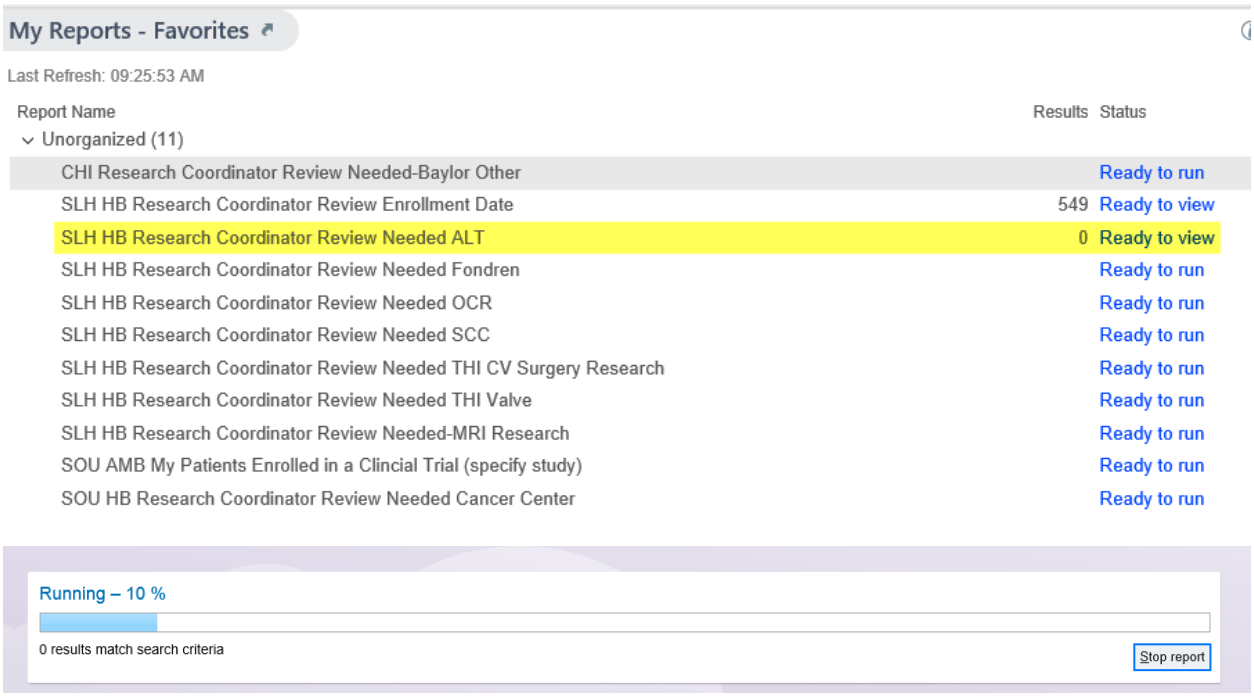
Any charges remaining on patient accounts after charge assignment will be billed routinely to the patient and/or patient's insurance.

Reference: BSLMC Policy & Procedure, *Billing Compliance – Research*

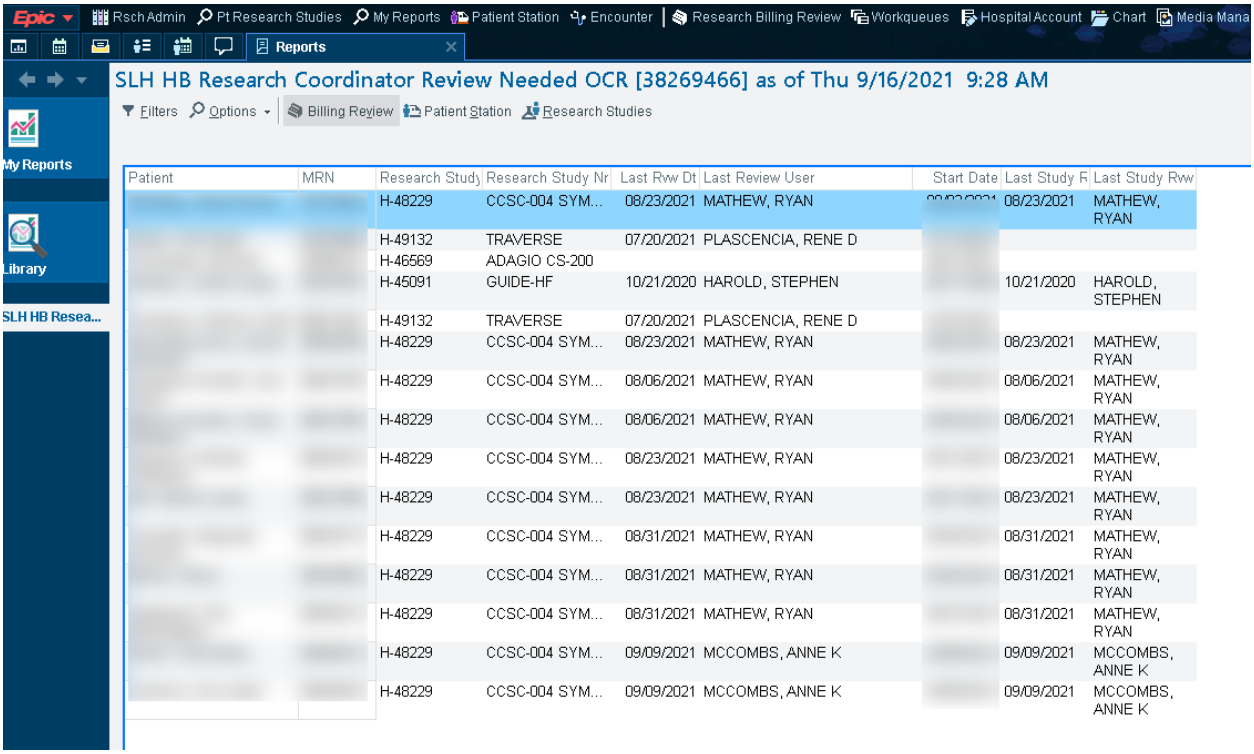
To find the Research Billing Review report, go to My Reports>Library and search for "Research". This will bring up all existing reports; see section *Patients Needing Research Billing Review – CHI*. You can find and "star" your report for easy identification.



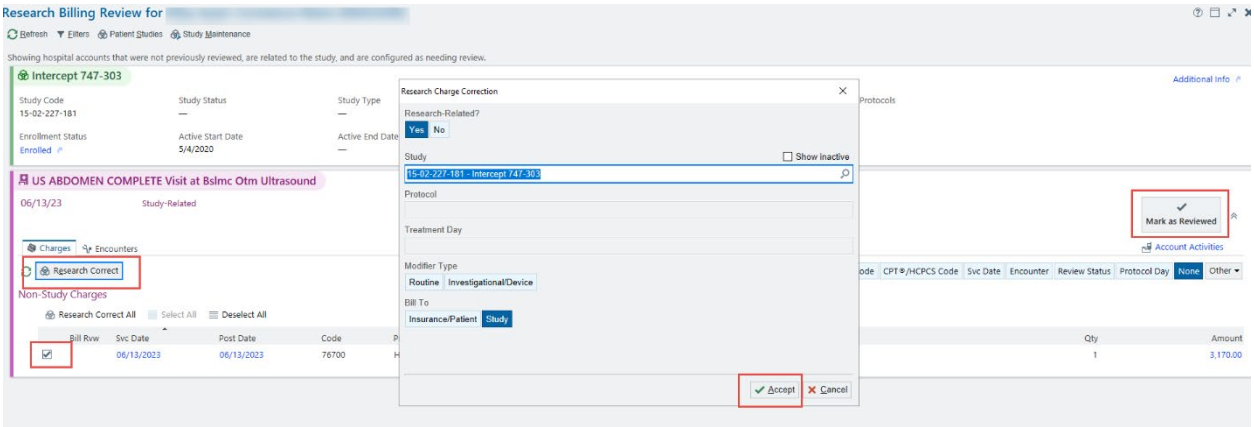

To view accounts ready for review, select your report and click *Run*. It may take a few minutes for the report to open.



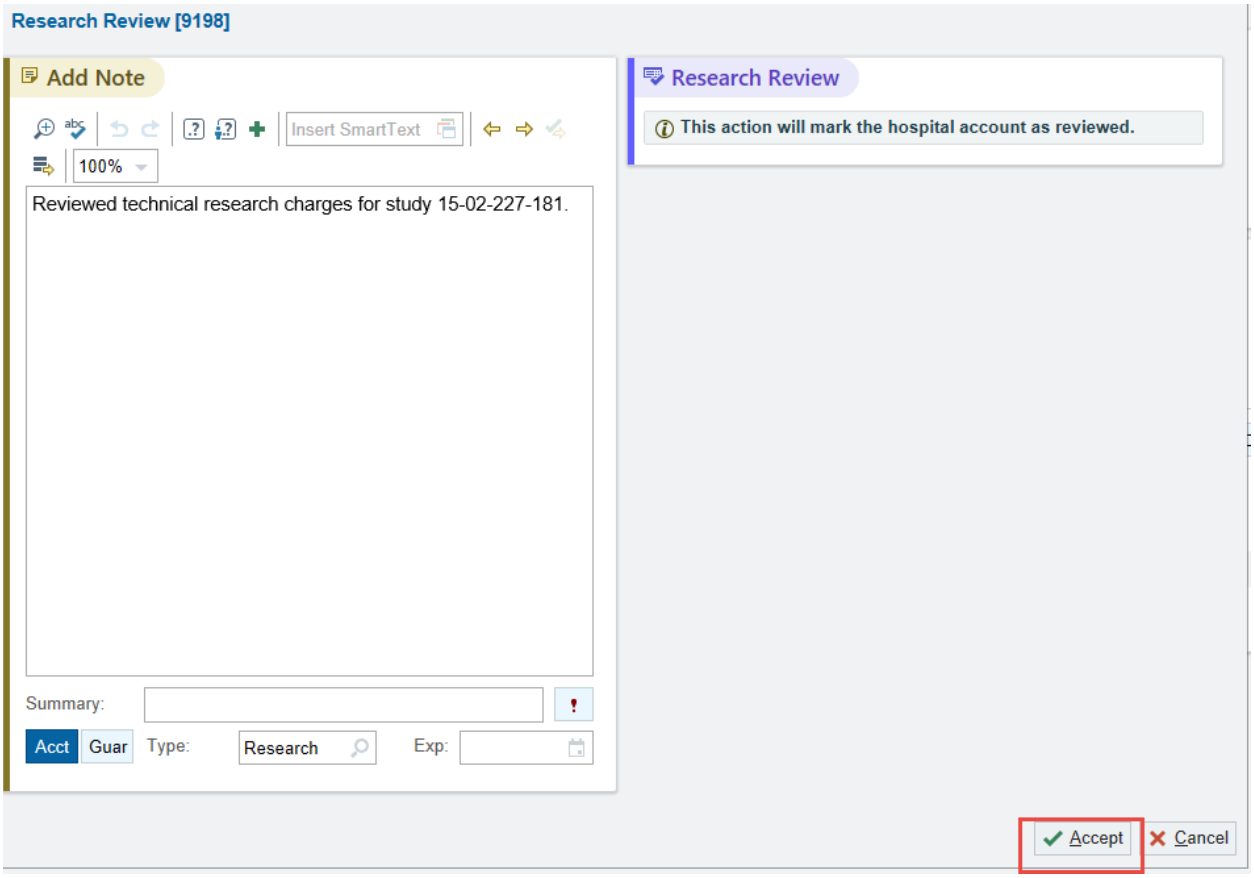

The report collates any patient records in the selected study billing review. Select the patient for review to open the account review screen.



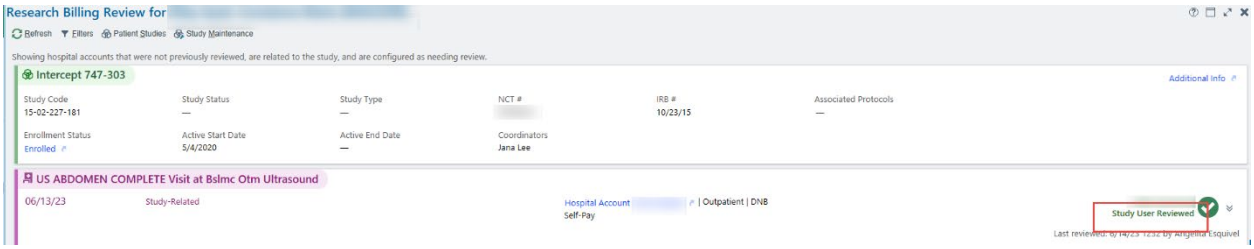
On this page, transfer charges considered research by clicking on the box next to the specific charge. When all research charges are selected, click on the *Research Correction* button, select *Research-related*, and select the correct study for charges. Uncheck *Patient/Insurance* if selected.




Click *Accept,* then *OK,* then *Refresh* button on the top left of your page and verify the correct charges transfer to the research study account. If correct, and there are no other charge transfers, click on *Mark Account as Reviewed* at middle right. Enter a note that the account was reviewed, then click *Accept.*



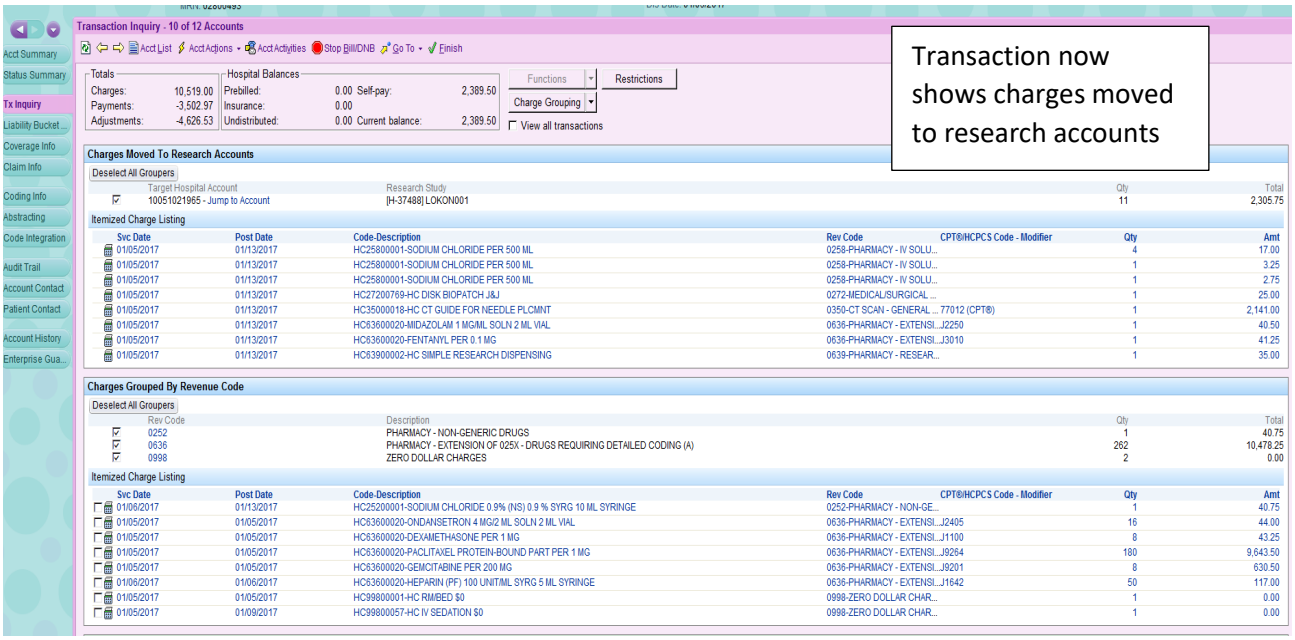

*Study User Reviewed* will appear on the account.




Clicking on *Charges* shows reviewed charges with a green check mark.


*Charges – Reviewed*

Transaction now shows charges moved to research accounts.




Transaction now shows charges moved to research accounts

## *Charge assignment for coordinators without Epic access*

Coordinators must review the clinical form and patient bill to correctly assign charges, as shown below:

CHI St. Luke's Health

## Clinical Form (FR2)

**Today's Date:** June 14, 2023

| | | |
|---|---|---|
| **FROM:** | PATIENT FINANCIAL SERVICES | M/C 1-266 |
| **ACCOUNT ANALYST** | | FAX#: 713-610-2008 |
| | | |
| **PATIENT NAME:** | | |
| **ACCT #:** | | |
| **MEDICAL RECORD #:** | | |
| **DATE OF SERVICE:** | | |
| **IRB# / ACCT. BALANCE:** | | |

***Please review the attached bill, for the above-mentioned patient. Please indicate below the proper information. Please return this information within 2 days to help expedite billing process.***

| | ***Circle correct answer*** | |
|---|---|---|
| Is this patient enrolled in this protocol/study? | Yes | No |
| **Is this patient account research related?** | Yes | No |
| Did patient have a research device or procedure? | Device | Procedure |
| ***Was device/procedure received on THIS date of service?*** | Yes | No |
| Is this patient a Screen Failure? | Yes | No |

| | ***Initial*** |
|---|---|
| ***Circle on itemized statement any services that are NOT standard of care. Indicate on itemized statement which research-related items are billed to the study account and which (if any) are billable to insurance.*** ***DO NOT ISSUE PAYMENT UNTIL YOU RECEIVE THE MONTHLY STUDY ACCOUNT INVOICE*** | |
| ***Whole claim Research Only, transfer all charges to Research Account.*** ***DO NOT ISSUE PAYMENT UNTIL YOU RECEIVE THE MONTHLY STUDY ACCOUNT INVOICE*** | |
| ***Whole claim Standard of Care, bill entire claim to insurance.*** | |

***COMMENTS:***

| |
|---|
| |
| |
| |

***Research Coordinator Signature:*** _____

***Date signed:*** _____

Sample Clinical Form for research visit, sent by Patient Financial Services to study team, along with patient bill. Coordinator should complete this form and indicate whether the associated bill is all research, all standard of care, or mixed. When only some items are research, these should be circled on the bill.

Baylor St. Luke's Medical Center

**For Payment Only:**
P.O. Box 4288
Houston, Texas 77210-4288

**All other Inquiries Write:**
P.O. Box 20805
Houston, Texas 77225-0805

CHI St. Luke's Health

Sample patient bill, sent with the above clinical form. Study team should circle any items on the bill that should be charged to the study account and return the bill and clinical form to Patient Financial Services.

| [redacted] | ACCOUNT NO. | GUARANTOR NO. | ADMIT DATE | DISCH. DATE | PAGE |
|---|---|---|---|---|---|
| | [redacted] | 2281565 | 07/14/2016 | 07/14/2016 | 1 of 1 |

DOCTOR
BAJAJ, MANDEEP

[redacted]

1 INSURANCE COMPANY
NONE

| GROUP NO. | POLICY NO. | INVOICE NO. |
|---|---|---|
| | | |

2 INSURANCE COMPANY
NONE

| GROUP NO. | POLICY NO. | INVOICE NO. |
|---|---|---|
| | | |

**CHARGES**

| Rev Code | Date | Procedure Code | Description of Service | Qty | Amount |
|---|---|---|---|---|---|
| 0610 | 7/14/16 | HC61000004 | HC MR ABDOMEN | 1 | 3,096.00 |

Total Charges: 3,096.00

Patient Financial Services will move all research charges to the study account and mark the account as reviewed. Any charges not marked as research are sent for standard clinical billing. All remaining charges will be billed to patient/insurance.

## *Monthly study account billing*

On the fifth (5th) of each month, BSLMC Patient Financial Services will send the study team an invoice for all charges assigned to the study account for the previous month. The study team should review the charges and work with Patient Financial Services to make any needed adjustments. The invoice should be paid within three months of receipt. If the study team expects a delay in payment, Patient Financial Services should be notified to avoid administrative hold on the study.

Reference: BSLMC Policy & Procedure *Billing Compliance – Research*

Baylor St. Luke's Medical Center

# BCM Clinical Research Center

The Baylor College of Medicine (BCM) Clinical Research Center (CRC), managed by the BCM Office of Clinical Research (OCR), provides both hospital-based and outpatient comprehensive infrastructure and nursing support to investigators who conduct patient-oriented clinical trials (Phase I-IV), metabolic studies, translational studies and pilot trials in all clinical areas. The CRC welcomes protocols funded by a variety of sources – federal, foundation or industry.

## *About the CRC*

*The **Inpatient CRC*** is a hospital-based unit located at Baylor St. Luke's Medical Center (BSLMC) (6720 Bertner Avenue) 20th floor inpatient unit. There are two dedicated inpatient research rooms to support early phase, complex, and overnight studies.

*The **Outpatient CRC*** is located at Baylor College of Medicine McNair Campus (7200 Cambridge St. Houston, TX, 77030). There are two dedicated research exam rooms on the 7th floor and an infusion suite on the 9th floor to support outpatient studies.

In addition to inpatient and outpatient facilities, the CRC also provides nursing support to Baylor's affiliated institutes, as applicable.

The CRC is staffed by a team of dedicated research nurses specially trained to perform simple to complex research studies. CRC staff work closely with study teams to ensure clinical study activities are conducted safely and appropriately, according to the workflow and sampling schedules of Institutional Review Board-approved protocols.

## *Cost Structure*

CRC rates are based on resource allocation of services provided, including CRC administrative startup and management, hourly staffing, CRC location, study funding source, meals, and basic medical supplies. All other procedures, tests, and supplies will incur a separate charge. Study teams must coordinate with the BSLMC Research Office during the administrative review process to obtain hospital pricing for research procedures. See CRC Cost Structure here: https://www.bcm.edu/research/research-offices/office-of-clinical-research/clinical-research-center/fee-schedule.

## *Resources and Services*

Nursing staff is trained to perform the following procedures. Annual competency-based training insures proficiency in these test procedures. Training for additional research specific procedures may be added as new studies are initiated.

- Two dedicated inpatient rooms
- Two dedicated outpatient exam rooms
- Outpatient infusion suite
- Lab processing area
- Refrigerated centrifuge and -80°C freezer
- EKG

- Basic medical supplies
- Vital signs, height and weight measurement
- Observation
- Assistance with physical examinations
- IV infusion pumps
- Phlebotomy and blood sampling per protocol
- Central/peripheral line access and site care
- Medication administration
- Adverse event management
- Patient meal services
- Access to BSLMC's pathology lab
- Access to BSLMC's dedicated research pharmacy

Study teams are encouraged to contact the CRC early in planning to discuss study needs. Please submit your request for support through the OCR online service request form at https://orit.research.bcm.edu/OCRServiceRequest/Login.aspx to initiate the CRC feasibility process. Also, see *Appendix V* for the CRC study initiation workflow. For more information about the CRC, please consult the Baylor College of Medicine Clinical Research Center Investigator's Manual, or contact the CRC at crc-support@bcm.edu.

## Device Study Impact Analysis

All device studies that require the hospital to purchase the device must undergo a financial impact analysis. This process provides for responsible allocation of hospital resources. For all investigational, humanitarian use, and post-market device studies to be conducted at the hospital, study teams must submit a request form to determine if their device study requires impact analysis. This process should be initiated as early in study startup as possible, as findings may impact study budgets.

If the device is provided free of charge by the sponsor, no analysis is required. If the hospital must purchase the device, impact analysis is required. The analysis is conducted by BSLMC Supply Chain and Finance, and is reviewed/approved by BSLMC executive leadership.

The impact analysis must be completed and approved by BSLMC leadership before administrative approval can be given and the hospital can purchase the device.

Please see the sample device assessment request form and impact assessment workflow in *Appendix VI*.

Reference: BSLMC Policy and Procedure, *Impact Assessment of Investigational/Humanitarian/Post-Market Devices - Research.*

# Appendix I

## *Instructions to provide view-only protocol access to BSLMC Research Office*

You may follow the below procedures to provide view-only access to your protocol submission to the BSLMC Research Office. You may also instead elect to manually submit the protocol documents with your BSLMC Administrative Application.

### Baylor College of Medicine IRB

Check the box for Baylor St. Luke's Medical Center as a site on the BRAIN ESP1 protocol submission.

### CommonSpirit Health IRB

Enter your protocol in the IRBNet system and share the project with Angie Esquivel and Kathleen Tulod of the BSLMC Research Office

### BRANY IRB

Add BSLMC as a site where research will be performed and provide view-only access to Angie Esquivel (aresquiv@bcm.edu) and Kathleen Tulod (Kathleen.tulod@bcm.edu).

Baylor St. Luke's Medical Center

# Appendix II

## *BSLMC Application for Administrative Review*

* Please visit https://www.stlukeshealth.org/locations/baylor-st-lukes-medical-center/research/conducting-research-baylor-st-lukes-medical-center for link to online application and Submitter/PI guide.

## *Sample Research Fee Schedule*

* Information will vary based on your study

Baylor St. Luke's Medical Center | Baylor College of Medicine

Baylor St. Luke's Medical Center
Office of Clinical Research
Baylor College of Medicine
6501 Fannin St., NA332A-B, BCM122
Houston, TX 77030

P 713.798.6024
F 713.610.2272
BSLMC_Research@bcm.edu

June 14, 2023

[PI Name & Address]

**RE:** **[IRB Protocol #]**
[Protocol Title]

**Pricing effective date**:
**Funding Source:** **Select**

**RESEARCH FEE SCHEDULE**

| Services | Charges per procedure | CPT | Charge Code |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

*PLEASE NOTE:*

- *This fee schedule covers only the procedures listed above as of the effective date for the study indicated. These prices may be used for budget negotiation with the study sponsor.*
- *The Principal Investigator is responsible for explaining the financial requirements for standard of care services to study participants.*
- *This fee schedule indicates cost per procedure; billing of services will be for actual utilization.*
- *All visits, tests or procedures required as routine medical care for research study patients will be billed to the patient or third party payer responsible for patient health care expenses.*
- *For questions regarding this fee schedule or otherwise, please contact the Research Office at BSLMC at 713-798-6024.*
- **Professional Charges:** BSLMC is unable to provide pricing for professional services. For pathology research pricing, please contact Lynn Bergeron (lynn.bergeron@medarms.com) at Community Pathology. For radiology research pricing, please contact Shelby Mujica (shelby.mujica@radpartners.com) at Singleton Associates.

The Principal Investigator's signature below indicates acceptance of the service charges described in this fee schedule.

Baylor St. Luke's Medical Center

**This fee schedule does not constitute BSLMC administrative approval of the study. This fee schedule merely represents BSLMC pricing for items identified as research for this study.**

_____ _____

Principal Investigator Signature Date

Baylor St. Luke's Medical Center

*Sample Request for Access to PHI for Research Purposes Form*

CHI St. Luke's Health

Baylor St. Luke's Medical Center

**Request for Access to Protected Health Information for a Research Purpose without Subject's Authorization**

**Instructions:** Research is defined in the HIPAA Privacy Rule as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." In order to comply with HIPAA and HITECH laws and regulations governing covered entities, individuals engaged in Research at Baylor St. Luke's Medical Center (BSLMC) must document their requests to use Protected Health Information (PHI) for research purposes without a patient's authorization. Researchers must complete and maintain a copy of this form for all such requests. A copy of the form must also be provided to the office providing access (such as Health Information Management), as applicable. Questions regarding this form or related regulations you should contact BSLMC_Research@bcm.edu

**Principal Investigator (PI) Name:**

_____

**PI Primary Institution/Employer:**

_____

**PI email/phone:**

_____

**Administrative contact name/email/phone:**

_____

**Research Project Title:**

_____

1. I hereby request to review individually identifiable health records for the named research project for which the Individual's authorization is not available. I represent that the PHI to which access is sought is necessary to the research and will be used solely for the named research project. My request is based upon the following authorization/justification. I have attached the required documents as indicated.

   ☐ Subject's written authorization WAIVED by IRB (full or partial waiver)
      1. Copy of IRB-approved waiver of consent
      2. Copy of IRB approval letter

   ☐ Decedents' health Information only.
      1. I agree that, upon request, I will provide documentation of the death of the individuals whose health information I will review.
      2. Brief description of research purpose and health information requested
      3. Copy of IRB approval letter

☐ Information is preparatory to research only. No PHI will be recorded or removed from the area of review.

1. I agree that no PHI will be emailed or stored on a flash drive, laptop, or otherwise recorded or removed from BSLMC (the "covered entity". I agree that health information will only be recorded in a manner such that the subject cannot be identified (identifiers include name, MRN, dates, etc.) I agree that if I want to record any identifiers including dates (of birth, service, etc.), then either a HIPAA waiver or subject authorization must be obtained. I understand that failure to abide by these conditions will result in automatic termination of access to PHI for research purposes.
2. Brief description of research purpose and health information requested

4. Type of health information to which access is requested

☐ Electronic records. Database to be queried: _____

☐ Paper records: Describe source/location

☐ Imaging

☐ Other: Describe

5. List all individuals who will have access to the requested PHI and their roles (i.e., co-investigator, study coordinator):

_____
_____
_____
_____

6. Please check one of the following:

☐ I have attached a list of records that I am requesting from Health Information Management. (The list must include the project title and PI name, full legal name of patient, patient's date of birth or SSN and medical record number when available).

☐ I am requesting that a list of records be generated for me by Health Information Management. I have attached a description of records I am looking for (include project title and PI name)

☐ I and/or the individuals listed above will directly access PHI under preexisting EPIC authorization and do not require assistance by Health Information Management.

***I agree that the information I have requested will only be used for the research purpose as stated in this form and its accompanying documentation. I will protect the confidentiality and security of this information while it is in my possession and will destroy identifiers if required by accompanying documentation.***

_____

Signature of Principal Investigator*

Baylor St. Luke's Medical Center

_____

Date

For HIM support, the completed form should be sent to Nanette Moreno, Systems Administrator, Health Information Management (nmoreno@stlukeshealth.org). No information can be released without IRB approval.

** Electronic or typed signatures are acceptable if form is sent from Principal Investigator's email address.*

Baylor St. Luke's Medical Center

# Appendix III

## *BSLMC Research Compliance Review – HIPAA Authorization Language*

## *List of Required Elements*

All studies submitted for BSLMC Administrative Approval will receive a compliance review from the BSLMC Research Office, prior to approval. The following items will be checked for each study.

| | | YES (X) | NO (X) |
|---|---|---|---|
| ☐ | **ICF Compliant with HIPAA Authorization Requirements (see attached)?**<br>**Comments:** | | |
| ☐ | **Is Full or Partial (select one) Waiver needed?** | | |
| ☐ | **Has Waiver been received?**<br>**Comments:** | | |
| ☐ | **Compliant with Conflict of Interest Requirements?**<br>**Comments:** | | |
| ☐ | **Involves other St. Luke's hospitals besides BSLMC (i.e. Woodlands, Lakeside, Sugarland, Vintage)?** | | |
| ☐ | **Is this an investigational drug study?** | | |
| ☐ | **Does the consent form state that abstinence is the only birth control method that is 100% effective?** | | |
| ☐ | **Further Regulatory Review Needed?**<br>☐ **Laser Committee Review**<br>☐ **Radiation Safety Committee Review**<br>☐ **IBC review needed**<br>☐ **MAC Authorization for Investigational Device Exemption (IDE)**<br><br>**Comments:** | | |
| **Other Comments or Review Considerations:** | | | |

| | | YES (X) | NO (X) |
|---|---|---|---|
| ☐ | ICF Compliant with HIPAA Authorization Requirements (see attached)?<br>Comments: | | |
| ☐ | Is Full or Partial (select one) Waiver needed? | | |
| ☐ | Has Waiver been received?<br>Comments: | | |
| ☐ | Compliant with Conflict of Interest Requirements?<br>Comments: | | |
| ☐ | Involves other St. Luke's hospitals besides BSLMC (i.e. Woodlands, Lakeside, Sugarland, Vintage)? | | |
| ☐ | Is this an investigational drug study? | | |
| ☐ | Does the consent form state that abstinence is the only birth control method that is 100% effective? | | |
| ☐ | Further Regulatory Review Needed?<br>☐ Laser Committee Review<br>☐ Radiation Safety Committee Review<br>☐ IBC review needed<br>☐ MAC Authorization for Investigational Device Exemption (IDE)<br><br>Comments: | | |
| Other Comments or Review Considerations: | | | |

## HIPAA Authorization Language – List of Required Elements

☐ Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).

☐ The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.

☐ The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.

☐ Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository).

☐ Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

**Authorization Required Statements** (see Privacy Rule, *45 C.F.R.* § 164.508(c) (2))

☐ The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.

☐ Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.

☐ The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.*

# Appendix IV

## *Sample Call Center/Registration Form*

CHI St. Luke's Health
Baylor St. Luke's Medical Center

### Call Center Research Visit Registration Form

Use this form for scheduling:
**RESEARCH STUDY PATIENTS***

**IRB # (study account):** _____
**Date Consent Signed**:**
**Total # pages, including this form:**

| | | |
|---|---|---|
| **Create a patient MRN:** | **YES** | **NO** |
| **If No, indicate Patient's current MRN:** _____ | | |

| | | |
|---|---|---|
| **Please call patient to schedule test:** | **YES** | **NO** |

| | | |
|---|---|---|
| **Please call patient to verify insurance:** | **YES** | **NO** |

**Test scheduling window (if applicable):**

(Research protocol requires tests to be done within this time frame. Call Center, please notify coordinator if any problems.)

| **Research Coordinator Use Only** |
|---|
| Ordering Physician: |
| Diagnosis: (no R/O or possible diagnosis) Z00.6, |
| Research Coordinator Name: |
| Contact Number: |
| Email: |

Please fax with orders and signed research informed consent form** to Call Center: 832-398-7728

Coordinators should contact the BSLMC Call Center at 832-355-0000, option 2 to confirm date/time scheduled.

**Comments:**

| **PATIENT INFORMATION** | | | | | |
|---|---|---|---|---|---|
| LAST NAME | | FIRST | MIDDLE INITIAL | TITLE (JR, MD, III) | |
| SSN | SEX ___M ___F | DOB (MM/DD/YY) | MARITAL STATUS ___SINGLE ___MARRIED ___DIVORCE ___WIDOW ___OTHER | | |
| MAILING ADDRESS | | | CITY | STATE | ZIPCODE |
| TELEPHONE (HOME) | CELLULAR | EMPLOYER NAME | | WORK NUMBER | |

* Non-Clinical Research Center patients only. Clinical Research Center (CRC) Patients must be scheduled through the CRC.

**Baylor St. Luke's Medical Center requires signed research informed consent forms be associated with research patients' electronic medical records for all studies utilizing informed consent. Call Center will attach the consent to the Epic MRN, if sent with this form. If consent has not yet occurred, fax consent when available to medical records for attachment: 832-355-2661.

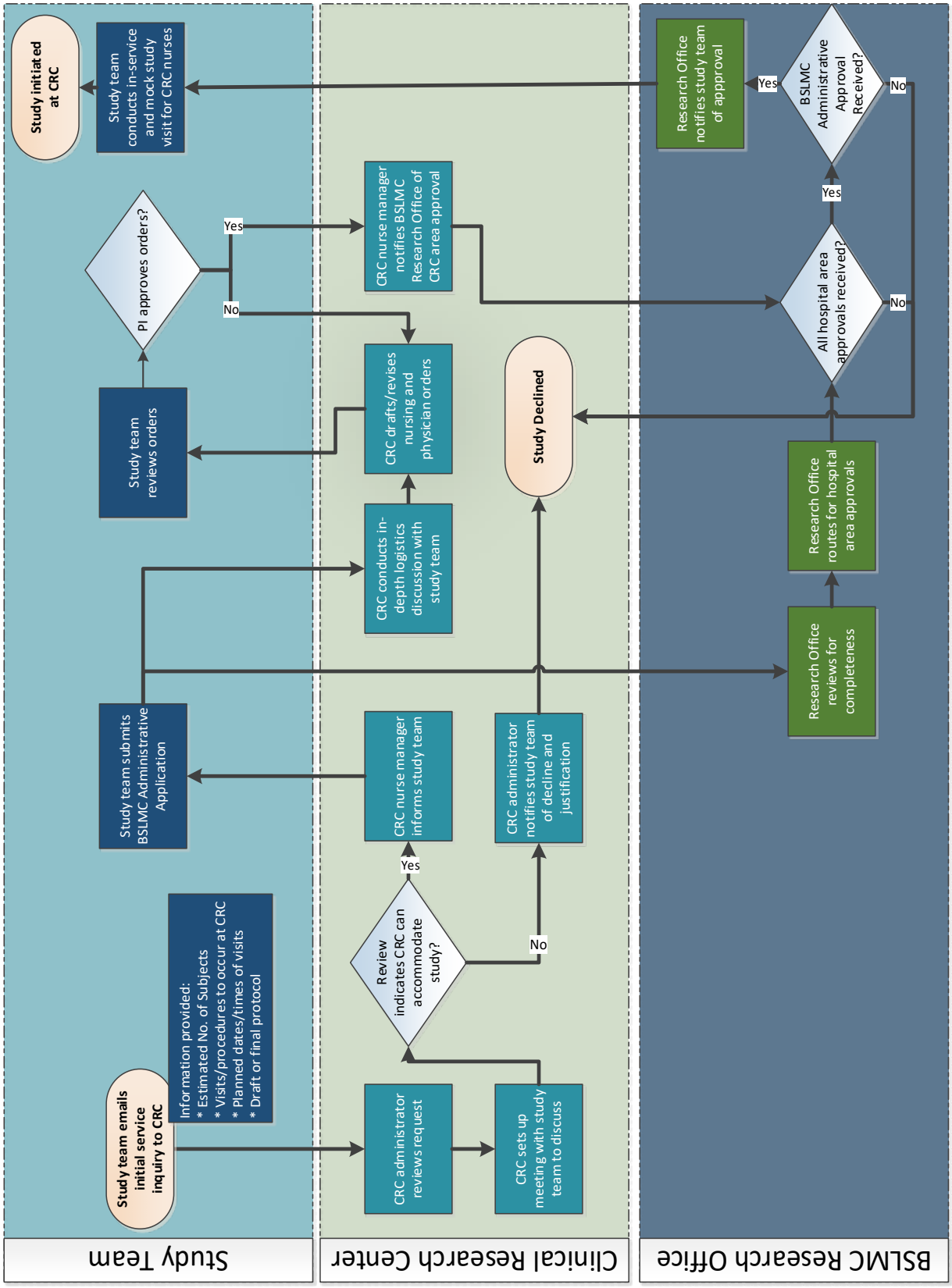
**For questions, contact the BSLMC Research Office at 713-798-6024**

Rev. 11.15.17 - Angie Esquivel

Baylor St. Luke's Medical Center

# Appendix V

# Clinical Research Center Study Initiation Workflow



Baylor St. Luke's Medical Center

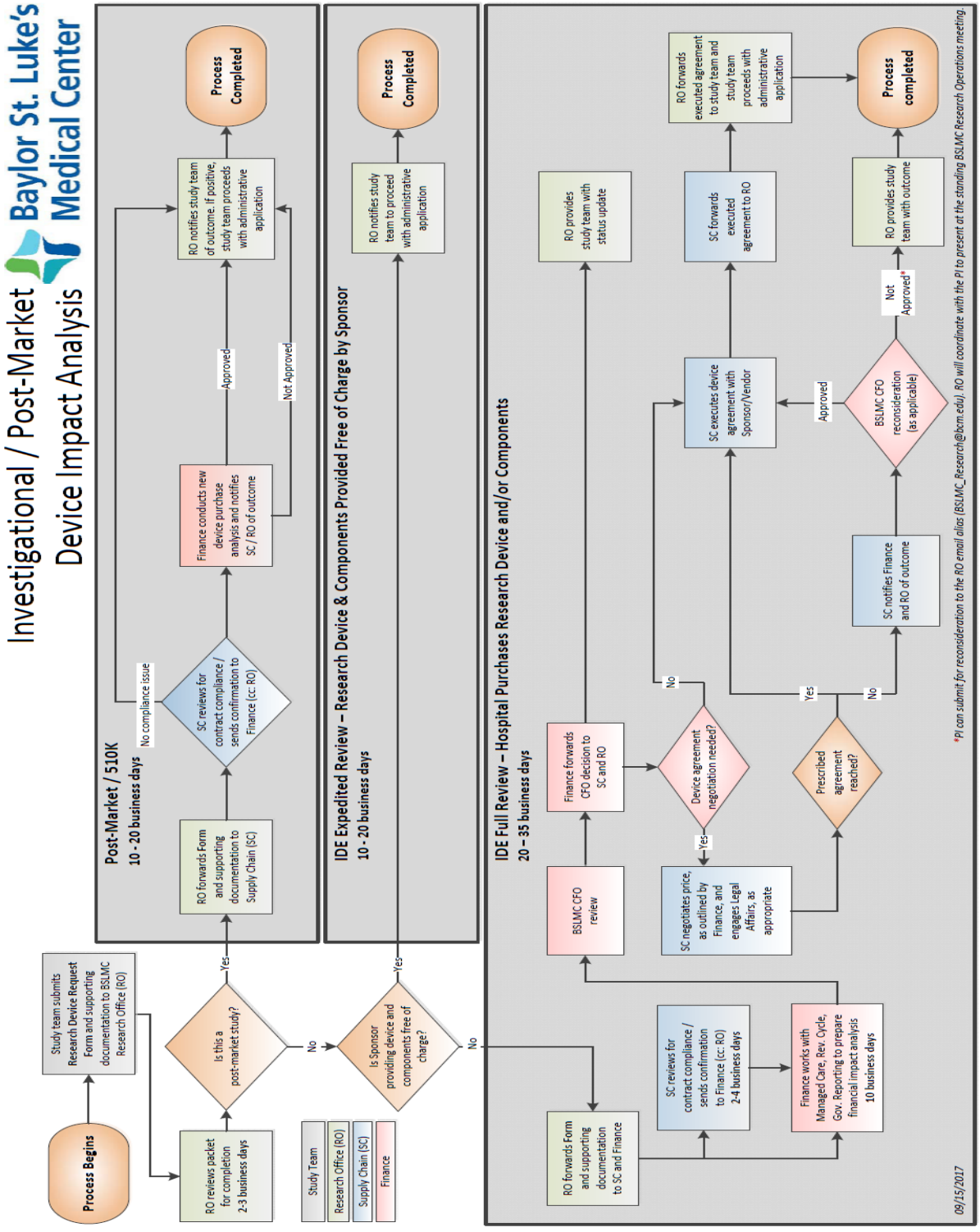
# Appendix VI

## *Device Impact Assessment Request*

Baylor St. Luke's Medical Center (BSLMC) requires hospital approval of investigational/humanitarian device purchase and purchase of approved devices not currently stocked by the hospital. Approval is based on an assessment of the financial and clinical impact to the hospital. The assessment should be completed prior to conducting budget negotiations with the sponsor.

All device studies conducted at BSLMC must have an approved device impact form before administrative approval can be provided. Please visit https://www.stlukeshealth.org/locations/baylor-st-lukes-medical-center/research/conducting-research-baylor-st-lukes-medical-center to submit a device form through the online application system.

*Impact Analysis Workflow*

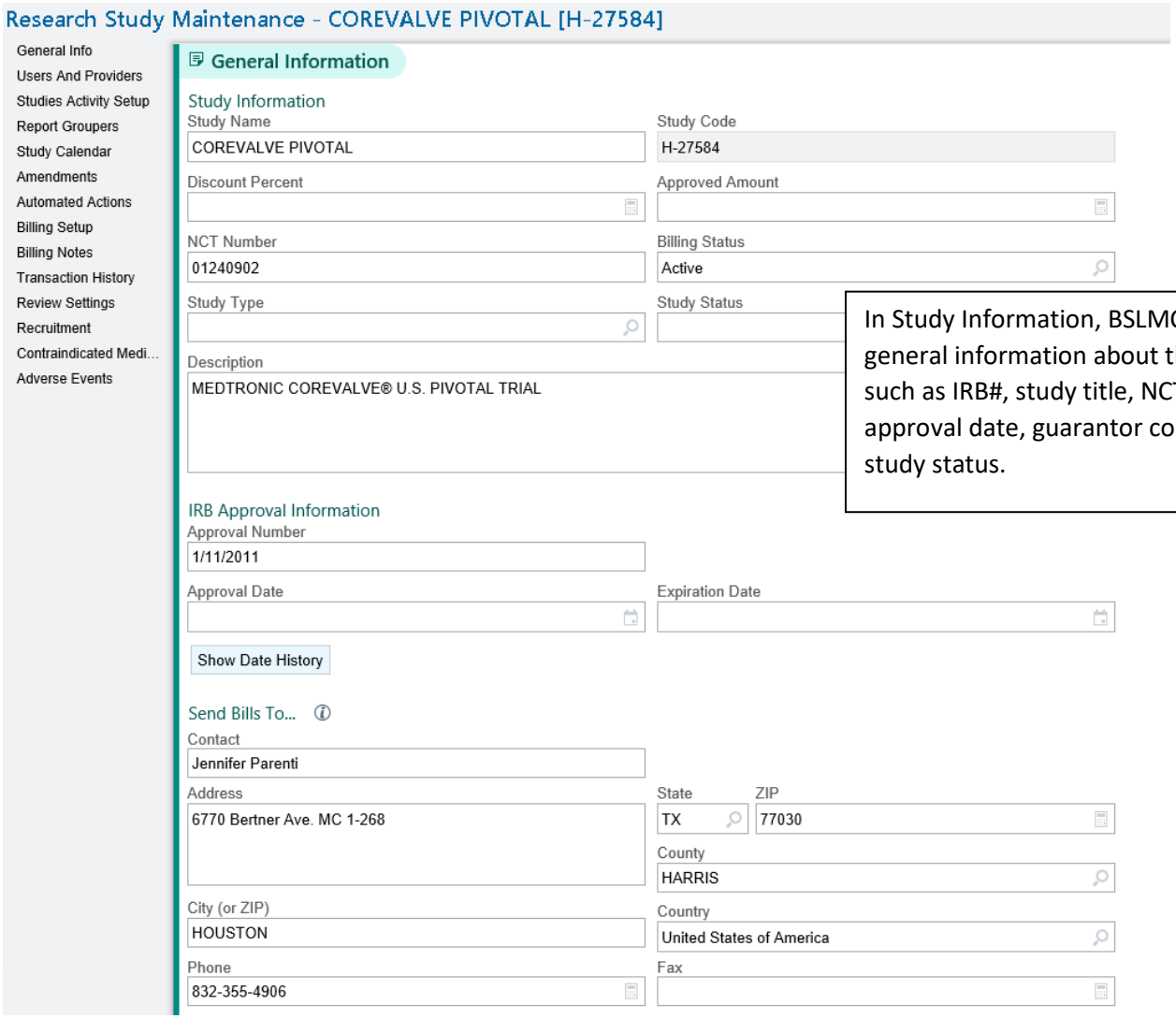


Baylor St. Luke's Medical Center

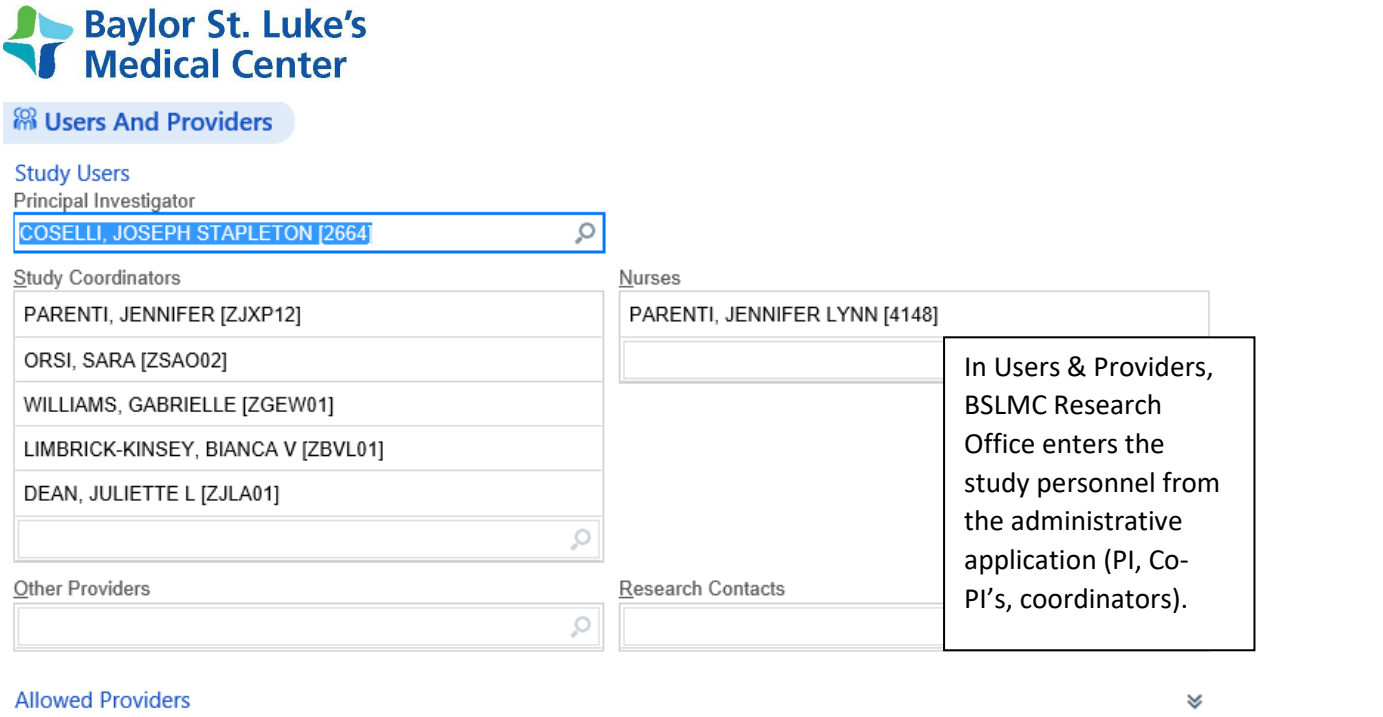
# Appendix VII

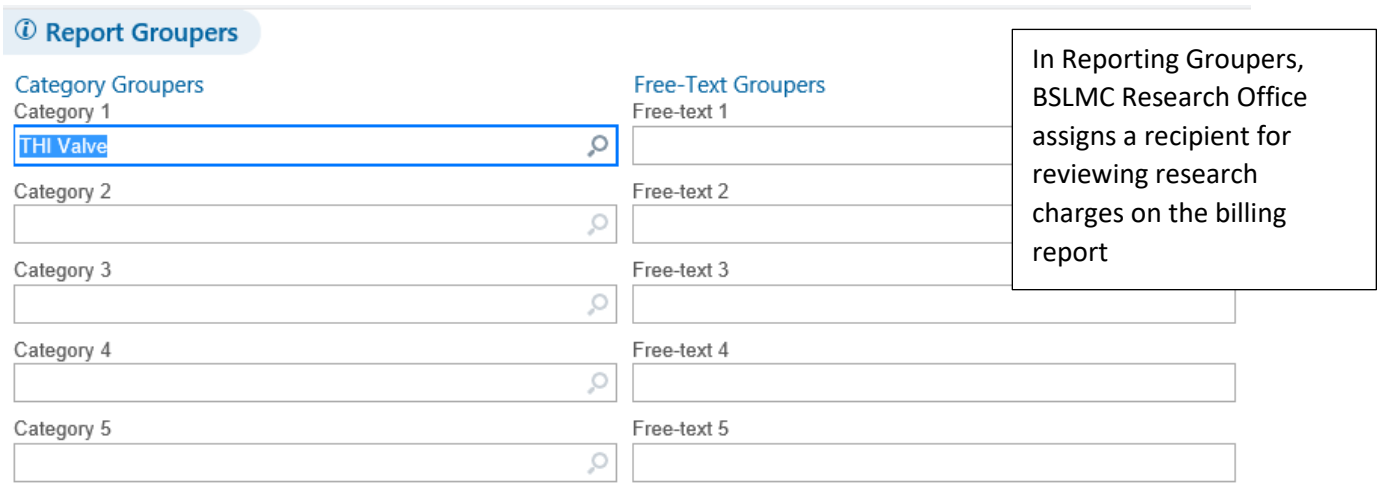
## *BSLMC Epic Study Build*

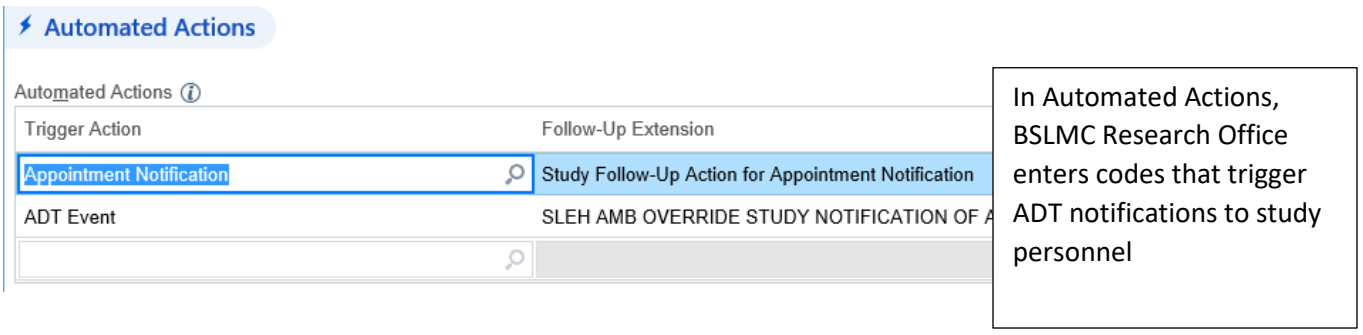
The below screenshots show the study information entered by the BSLMC Research Office when setting up your study in Epic, following administrative approval.

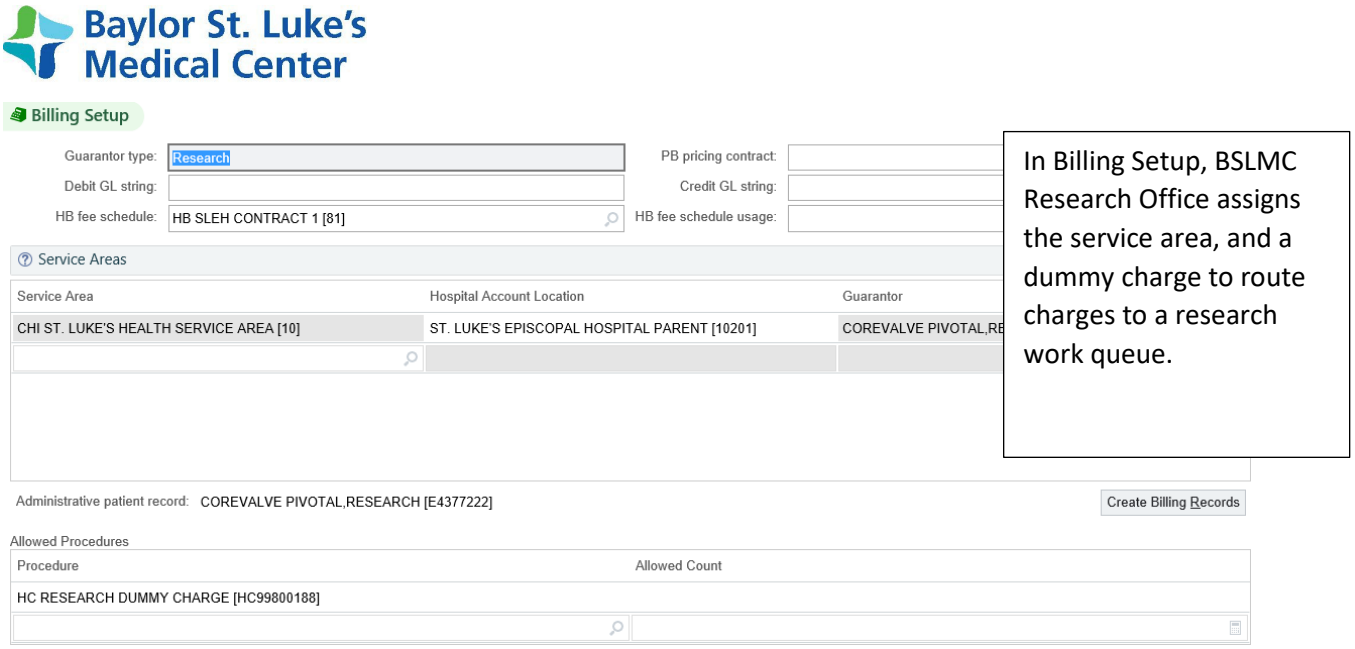



In Study Information, BSLMC enters general information about the study such as IRB#, study title, NCT#, IRB approval date, guarantor contact, and study status.

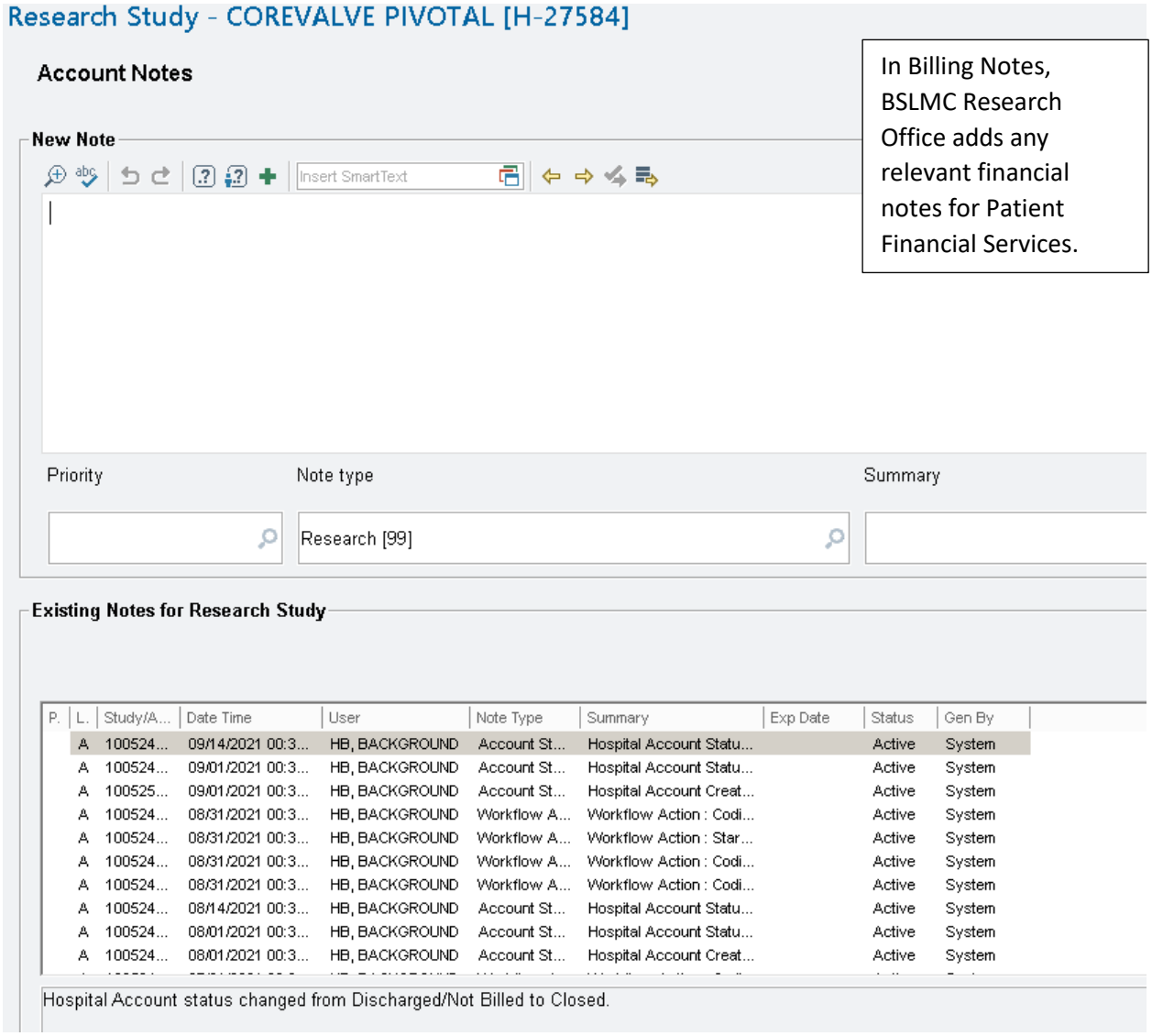

Baylor St. Luke's Medical Center
Users And Providers
Study Users
Principal Investigator
COSELLI, JOSEPH STAPLETON [2664]
Study Coordinators
PARENTI, JENNIFER [ZJXP12]
ORSI, SARA [ZSAO02]
WILLIAMS, GABRIELLE [ZGEW01]
LIMBRICK-KINSEY, BIANCA V [ZBVL01]
DEAN, JULIETTE L [ZJLA01]
Nurses
PARENTI, JENNIFER LYNN [4148]
Other Providers
Research Contacts
Allowed Providers
In Users & Providers, BSLMC Research Office enters the study personnel from the administrative application (PI, Co-PI's, coordinators).


Report Groupers
Category Groupers
Category 1
THI Valve
Category 2
Category 3
Category 4
Category 5
Free-Text Groupers
Free-text 1
Free-text 2
Free-text 3
Free-text 4
Free-text 5
In Reporting Groupers, BSLMC Research Office assigns a recipient for reviewing research charges on the billing report

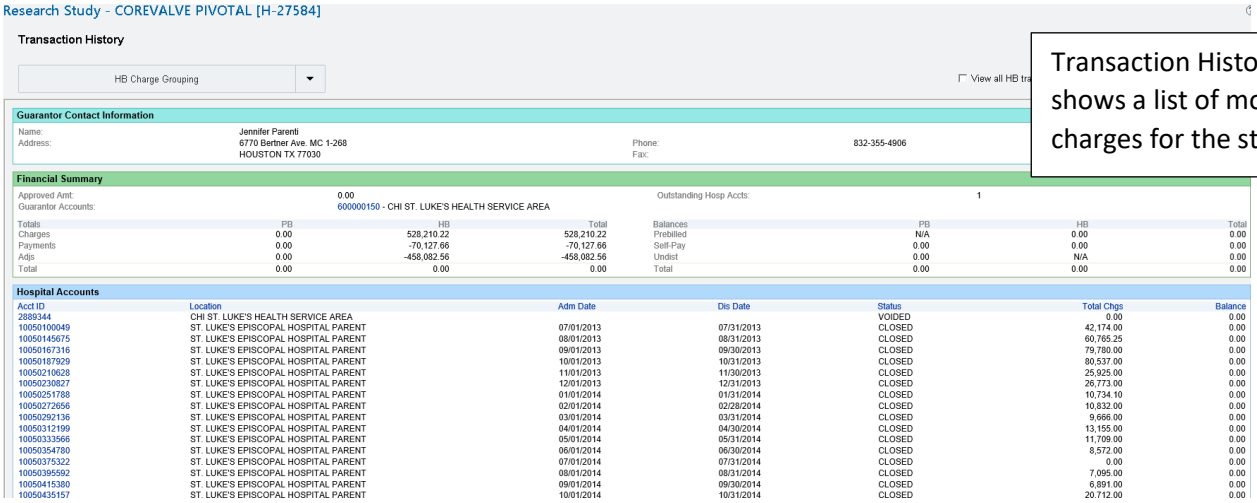

Automated Actions
Automated Actions
Trigger Action
Follow-Up Extension
Appointment Notification
Study Follow-Up Action for Appointment Notification
ADT Event
SLEH AMB OVERRIDE STUDY NOTIFICATION OF A
In Automated Actions, BSLMC Research Office enters codes that trigger ADT notifications to study personnel




In Billing Setup, BSLMC Research Office assigns the service area, and a dummy charge to route charges to a research work queue.




In Billing Notes, BSLMC Research Office adds any relevant financial notes for Patient Financial Services.



Research Study - COREVALVE PIVOTAL [H-27584]

Transaction History

HB Charge Grouping

View all HB tra

**Guarantor Contact Information**

| | | | |
|---|---|---|---|
| Name: | Jennifer Parenti | | |
| Address: | 6770 Bertner Ave. MC 1-268<br>HOUSTON TX 77030 | Phone: | 832-355-4906 |
| | | Fax: | |

**Financial Summary**

Approved Amt: 0.00

Guarantor Accounts: 600000150 - CHI ST. LUKE'S HEALTH SERVICE AREA

Outstanding Hosp Accts: 1

| Totals | PB | HB | Total |
|---|---|---|---|
| Charges | 0.00 | 528,210.22 | 528,210.22 |
| Payments | 0.00 | -70,127.66 | -70,127.66 |
| Adjs | 0.00 | -458,082.56 | -458,082.56 |
| Total | 0.00 | 0.00 | 0.00 |

| Balances | PB | HB | Total |
|---|---|---|---|
| Prebilled | N/A | 0.00 | 0.00 |
| Self-Pay | 0.00 | 0.00 | 0.00 |
| Undist | 0.00 | N/A | 0.00 |
| Total | 0.00 | 0.00 | 0.00 |

**Hospital Accounts**

| Acct ID | Location | Adm Date | Dis Date | Status | Total Chgs | Balance |
|---|---|---|---|---|---|---|
| 2889344 | CHI ST. LUKE'S HEALTH SERVICE AREA | | | VOIDED | 0.00 | 0.00 |
| 10050100049 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 07/01/2013 | 07/31/2013 | CLOSED | 42,174.00 | 0.00 |
| 10050145675 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 08/01/2013 | 08/31/2013 | CLOSED | 60,765.25 | 0.00 |
| 10050167316 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 09/01/2013 | 09/30/2013 | CLOSED | 79,780.00 | 0.00 |
| 10050187929 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 10/01/2013 | 10/31/2013 | CLOSED | 80,537.00 | 0.00 |
| 10050210628 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 11/01/2013 | 11/30/2013 | CLOSED | 25,925.00 | 0.00 |
| 10050230827 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 12/01/2013 | 12/31/2013 | CLOSED | 26,773.00 | 0.00 |
| 10050251788 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 01/01/2014 | 01/31/2014 | CLOSED | 10,734.10 | 0.00 |
| 10050272656 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 02/01/2014 | 02/28/2014 | CLOSED | 10,832.00 | 0.00 |
| 10050292136 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 03/01/2014 | 03/31/2014 | CLOSED | 9,666.00 | 0.00 |
| 10050312199 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 04/01/2014 | 04/30/2014 | CLOSED | 13,155.00 | 0.00 |
| 10050333566 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 05/01/2014 | 05/31/2014 | CLOSED | 11,709.00 | 0.00 |
| 10050354780 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 06/01/2014 | 06/30/2014 | CLOSED | 8,572.00 | 0.00 |
| 10050375322 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 07/01/2014 | 07/31/2014 | CLOSED | 0.00 | 0.00 |
| 10050395592 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 08/01/2014 | 08/31/2014 | CLOSED | 7,095.00 | 0.00 |
| 10050415380 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 09/01/2014 | 09/30/2014 | CLOSED | 6,891.00 | 0.00 |
| 10050435157 | ST. LUKE'S EPISCOPAL HOSPITAL PARENT | 10/01/2014 | 10/31/2014 | CLOSED | 20,712.00 | 0.00 |

Transaction History shows a list of monthly charges for the study.