

Research Revenue Integrity

Responsible for ensuring all technical and professional services provided under a clinical research study at any UC Irvine Health location are identified, coded, recharged and/or billed correctly.



UC Irvine Health

What is Research Revenue Integrity...

- Secure CMS & Medicare Administrative Contractor (MAC) coverage approval for FDA-approved IDE Categories A & B device studies
- RRI signoff on behalf of UC Irvine Health (study activation requirement), including review and approval of all coverage analysis (e.g. new and amendment study requests)
- Research patient enrollment and tracking
- 100% review of hospital & professional research billing activities
- Research charge master/Research rate quotes
- Ancillary Support



Secure Medicare Coverage for FDA-approved IDE Categories A & B device studies through CMS and Noridian (Medicare Administrative Contractor)

Secure CMS Coverage & Analysis and Noridian (MAC) coverage approval for Categories A and B FDA IDE approved devices in order to bill insurance for routine items and services related to the device.

- Submit application for coverage approval on IDE FDA devices dated before January 1, 2015 and after January 1, 2015 for which UC Irvine faculty is the holder of the IDE.
- Obtain coverage approval from sponsoring agency on IDE FDA devices dated after January 1, 2015.

Maintain coverage approval throughout the life of the clinical research study.

- Submit amendments of the IDE approved study that result in changes to the study design and updates to the risk/benefit ratio that may warrant further review based on impact to beneficiaries.
- Upon notification of study closure, submit notice to CMS and Noridian of the device study end date, only when UC Irvine Health is the owner of CMS approval for coverage.

RRI signoff on behalf of UC Irvine Health (study activation requirement), including validation of all coverage analysis (e.g. new and amended study requests)

Quality assurance review (requirement for all clinical research studies that utilize medical center items and services) and validation of coverage analysis

- Verify accurate coding and billing rules & principles are applied
- Confirm the appropriate research charge master rates are applied
- Identify applicable service area practices
- Ensure delineation of drugs, devices, and/or services provided at no cost to UC Irvine Health patients.
- Review of study related procedures and costs/reimbursement language referenced in the informed consent form (ICF) that may fall under patient financial responsibility. If applicable, provide recommendations to study team to submit for sponsor & IRB review/approval.
- Provide guidance on contract related payment terms to assure language supports compliant billing practices. If applicable, provide recommendations to appropriate business owners to replace unfavorable language.

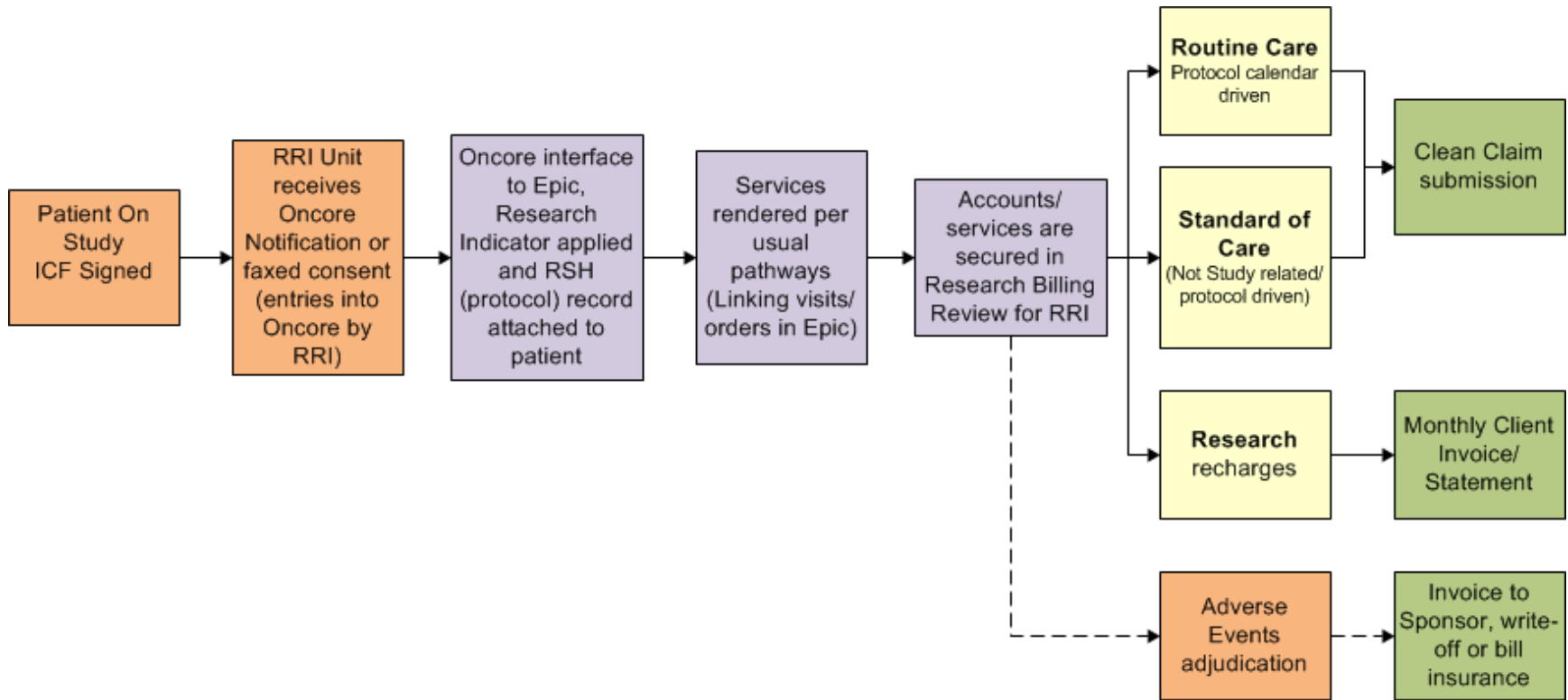
Research protocol activation, patient enrollment and tracking

- Management of Epic research record
 - Activate at time of enrollment/open to accrual
 - Complete/Close at study closure
 - Ensure all research services have been recharged and paid
- Management of Oncore to Epic interface subject/protocol status notifications (RPE interface)
 - Open to Accrual
 - Consent
 - Eligible/Ineligible
 - Withdrawn
 - Treatment/Follow-Up
 - Off Study
 - Suspended (e.g., FDA hold, amendment approval)
 - Closed to Accrual
 - IRB Study Closure

100% review of hospital & professional research billing activities

- Reconcile to Coverage Analysis, ICF, research budgets and clinical trial agreements/research agreements for study related items and services.
- Validate authorizations in Epic for routine care services, verify MD orders, results, physician documentation and the Medication Administration Record for medications administered in Infusion Centers.
- Adjudicate line item charges to deliver a clean claim and accurate recharge to the study team while adhering to billing timelines.

Research Billing Process Flow



	Research team (CRC, PI)
	RRI Unit
	Determination of claim management
	Provision to funding source

Research Statements

- Study paid research related items and services that are designated through account review are billed on monthly research statements.
- RRI Analysts submit monthly statements to first level approvers. Upon approval forward to HB & PB payment posting and facilitate interdepartmental KFS transfers.

Liaison support for research patient billing inquiries

- RRI serves as a resource to study teams, HB and PB Billing offices, and our front end clinical partners.
- Perform a complete review and resolution of professional and technical billing questions related to research services.
- Financial Counseling
 - RRI works directly with the Hospital Financial Counselor to provide advisement on the financial obligations of the patient and the institution, related to study services.

Adverse Event Sponsor Invoicing

- UCOP Memo 95-5
 - “Provides requirements regarding the provision or reimbursement of medical treatment to subjects participating in the testing of drugs or devices pursuant to a private sponsor’s protocol.”
 - “Requires the sponsor to reimburse for injuries that extend beyond those caused by a study drug or device.”
 - Identification of adverse events comes through account management, clinical documentation review, and/or study team notification. PI attribution of the event is obtained, and all related charges are held.

Research Charge Master/Research rate quotes

- Oncore Charge Master
 - Responsible for annual updates and performs routine quality assurance of the Charge Master to ensure the appropriateness of CPT's, HCPCS, cost centers, rates and descriptions.
- Research Rate quotes
 - In collaboration with study teams and School of Medicine, perform projected cost analysis of research services. Ensure appropriate charge capture is accounted for to secure an accurate budget proposal.

IDS Pharmacy Support

- Secure revenue for IDS Pharmacy study fees through reconciliation and recharge submission
 - PDX – Oral dispensation
 - Intravenous compounding and dispensation of investigational drugs
 - Study start up

We are here to support you...

- **Jennifer Greenlund, CPC, COC (657) 284-7001**
Assistant Director
- **Anya Dang, CPC (657) 284-7009**
Revenue Clinical Trials Analyst
- **RRI Account Analysts**
 - **Mario Ortiz (657) 284-7007**
 - **Rita (Maria) Pagkalinawan (657) 284-7006**
 - **Angelique Johnson (657) 284-7004**
 - **Sophia Perez (657) 284-7005**
- **RRI Fax (888) 972-7973**
- **ResearchRevenueIntegrityCRBCRFA@hs.uci.edu**