



Clinical Research Billing Process

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT
HOUSTON

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HISTORY

- Office of Inspector General priorities
 - Inappropriate clinical research billing
 - Double dipping
 - Residual funding of federal funds
 - Effort reporting



Why is this Important?

- ▣ If a bill is submitted in error to Medicare or Medicaid and is paid, this constitutes fraud under the False Claims Act
- ▣ If a bill is submitted to a third party payer and is paid AND the sponsor reimburses for the same service, this is “double dipping” and constitutes fraud



A CLINICAL RESEARCH BILLING COMPLIANCE PROGRAM

Identified compliance risks for clinical research billing

- **Risks 1, 2** - inappropriately billing Medicare for items or services in a clinical trial that are ineligible or covered by a grant/contract
- **Risks 3, 4, 5, 6** - failing to recover costs of clinical trials
- **Risk 7** - inappropriately using research funds for clinical care
- **Risk 8** - failing to maintain documentation to support Medicare charges

Reviewed current UTHSCH clinical research billing processes

- **Focused on billing related issues in three phases of clinical studies** - pre-award, study-initiation, and study-administration
- **Focused on processes in Medical School Depts. using IDX for patient scheduling and billing**

Identified requirements for billing compliance program

- Document all costs in budgets
- Identify parties responsible for costs in budgets
- Require OSP review/approval of study budgets
- Link study budgeting, initiation, and administration activities to share information required for accurate billing
- Use standard rates for UTHSCH clinical services in research studies
- Implement compliance programs that meet UTHSCH, UT-System and Federal requirements

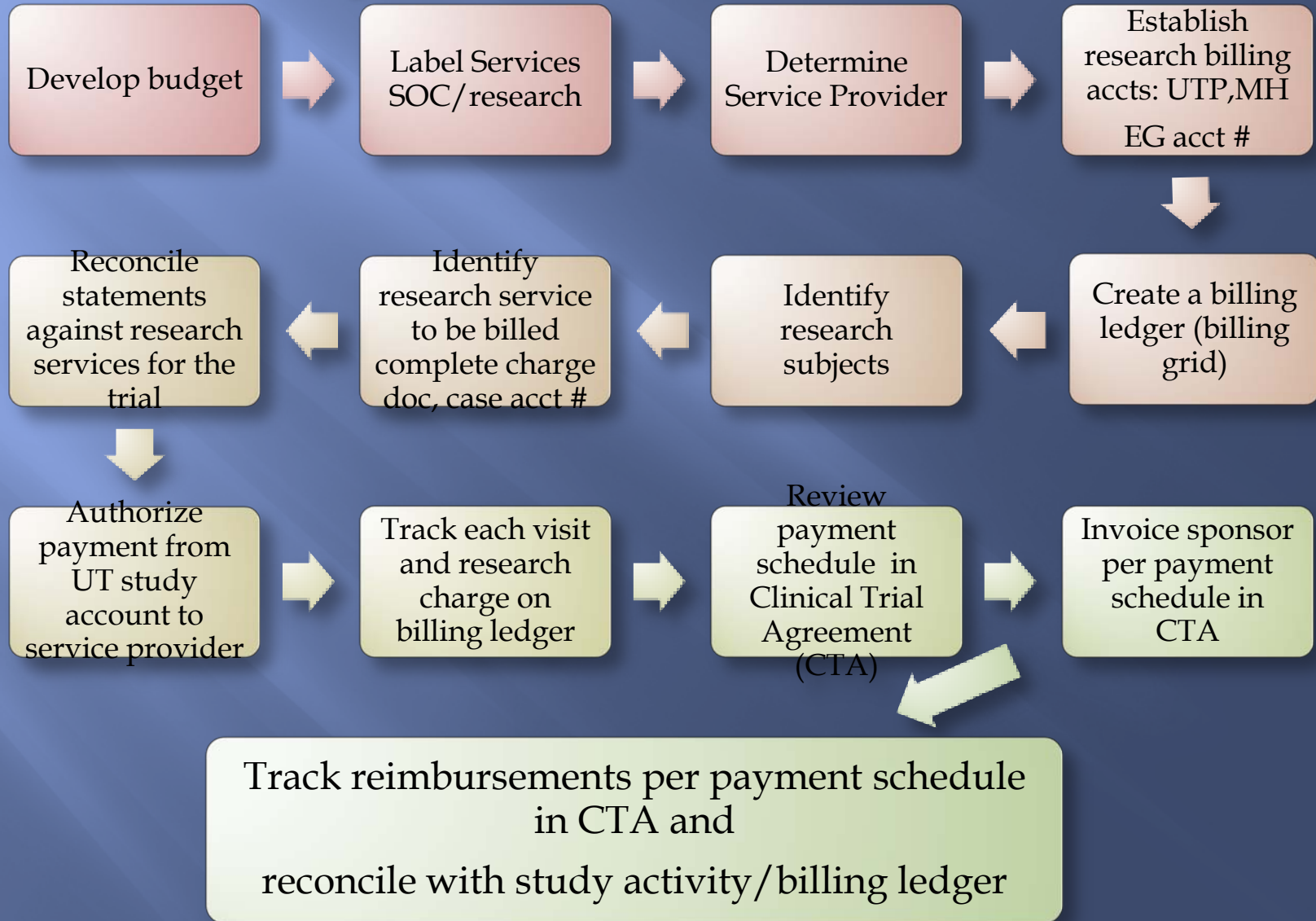


Billing Objectives

- ❑ Simplify and clarify the clinical research billing processes.
- ❑ Ensure full cost recovery of clinical research studies.
- ❑ Reduce the risks of inappropriately billing patients and/or third parties.



Clinical Research Billing Responsibilities Overview



UTHSC-H Clinical Trials Study Initiation Flowchart

STUDY ACCOUNT SET UP PROCESS

OSP (contract executed)
notifies PAF Team
Establishes UT Study Acct

**External Billing Account
Set Up**
- At Affiliate Site

UT Physicians Billing Department:
Establish Research Study Case Acct
Research Coordinator:

Complete Research Account Set Up Form for each dept.providing svcs

- Dept/ PI/ Coordinator,CPHS # Title, sponsor, research services, CPT codes, and charges to be billed to sponsor
-DMO sign off ▲

**MHHS
approval
w/acct and
price list**

**HCHD
Approval**

PAF Team
Sends Account Notification
to: PI/Department/ OSP

**CRU
coordinator
services**

For IDX,
Research Coordinator: Transmit
- Research Account Set Up Form
- Short Overview of Protocol to:
1. Case Billing Department:
FAX: 713-500-8500
Email: Sandra.Quinones@McKesson.com
Phone: 713-500-8719 and
2. Specific department and UCP Clinic
Physician Office Administrator

STUDY INITIATION



UT Research Billing Account Set Up

- Provide a brief description of research population on Form
- Transmit Research Account Set-up Form to:
Sandra.Quinones@McKesson.com
Case Billing Department
Fax: 713-500-8500
Phone: 713-500-8719
- Transmit Research Account Set-up Form to specific department and/or UCP Clinic Physician Office administrator

CLINICAL RESEARCH BILLING PROCESS

Patient Scheduled for UT Service
(Inpatient or Outpatient)

Generates Research Charge

Generates Standard of Care
Charge

Research Service Billable to Research Study
-Schedule as Research Subject/Service,

Research Service is Standard of Care and/or Billable to
Patient/ third Party
- Schedule as Standard Treatment

UT Research Service/ Professional or consulting fee Or

MHH/HCHD Service (Technical component)

Coordinator:

- Complete UT Clinical Trial Services Form/ Charge Document
- Transmit Form to designated UT department research contact and keep copy in study file

Coordinator:

- Notify outside institution per institutional policy

Department research charge entry personnel:

- Establish case account for subject,
- Transmit charge document to other departments that provided research services
- Enter charge into IDX

UTP generates statement to PI

MHH/HCHD/CRU generates statement to PI

PI/ Research Coordinator:

- Reconcile/ correct research services charges
- Generate Invoice to Sponsor, if indicated, per Study Compensation Schedule in CTA

PI/ Research Coordinator:

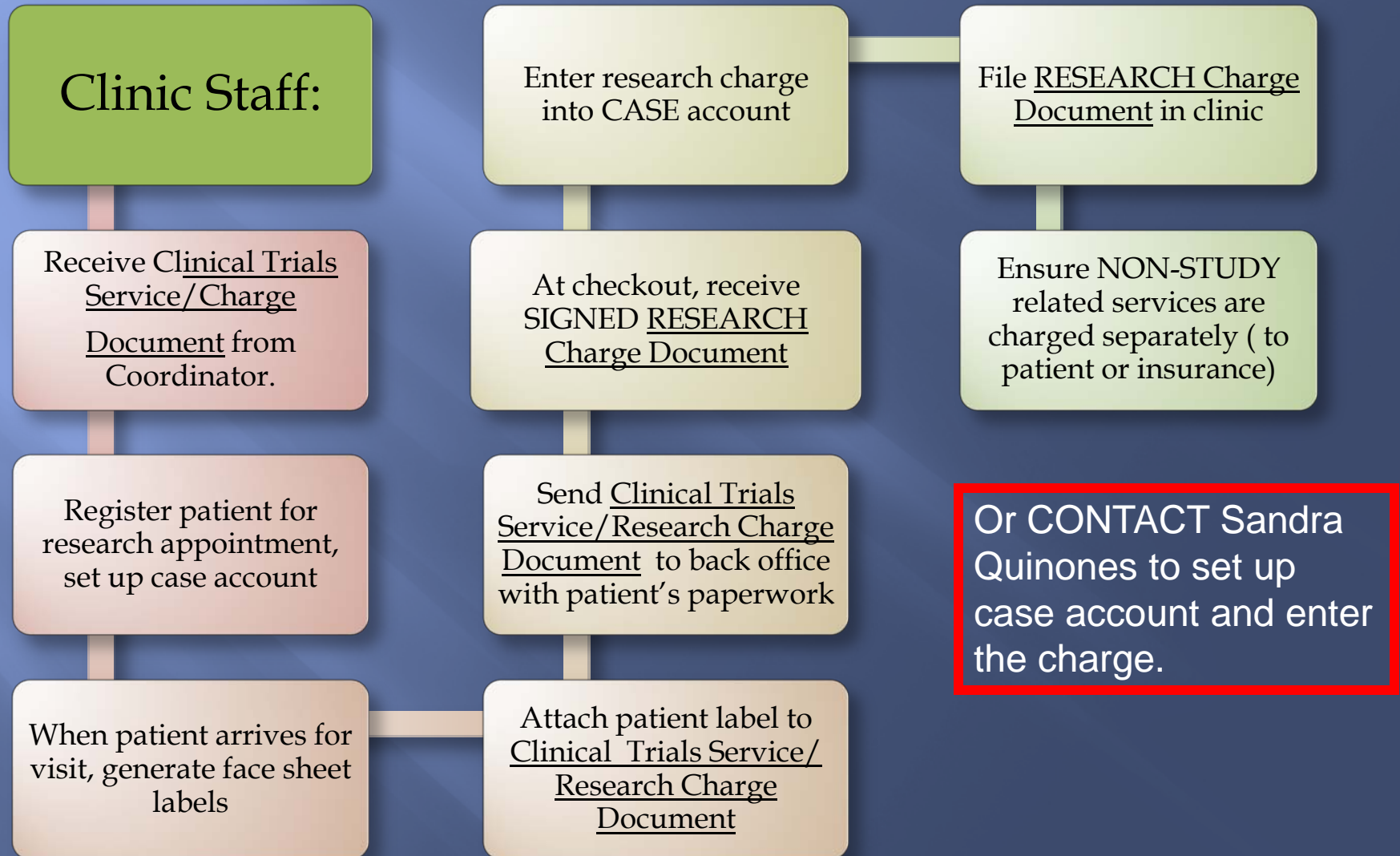
- Approve payment and notify PAF to pay from Study Account

PAF Team Study Account:

- Receive Revenue from Sponsor
- Pay UTP and/or External Billing System for Research Related Charges



Service Charge Entry Process





Invoicing Process

Statement is generated and sent to investigator by service department (UTP)



Investigator/Coordinator receives and reconciles statement for research services



Department generates voucher statement to PAF for payment

**If dept. invoicing is done
(Non federal Trials)**



Coordinator notifies department admin when services requiring invoice to sponsor are performed



Dept. administration generates an invoice per clinical agreement and/or as services are provided



Financial Management

- Communication between research coordinator and administrator
 - Set up schedule for communicating research visits/items and services performed
 - Review CTA payment schedule- milestone payments
 - Review UT study account at least monthly-



- Set up study ledger (billing grid)
 - Includes all visits, each charge for visits
 - Can be listed as visit 1 and total reimbursement for that visit



Financial Management

- Review all statements
- Reconcile statements with study visit schedule –
- Reconcile reimbursement from sponsor with CTA budget
- Prepare invoices – refer to CTA budget
- Ensure indirect costs are included to invoice total –
(should be in CTA budget)





Milestone Payments

- ▣ Payments that are based on completion of specified items during the study and outlined in the Clinical Trial Agreement
 - Certain number of subjects enrolled
 - Completion and collection of case report forms
 - End of study payment

Example- payment for 5 enrolled subjects, or completion of each 5 completed CRFs



Unit Payments

- Sponsor pays for each research service completed
- Based on actual work performed, triggers a payment to be sent
- Example- payment for visit one that includes ECG, labs, survey, PE
- Specified in CTA budget



Billing SUCCESS

DEPENDS ON:

- Following UT Policy
- Detailed tracking of the subject's activities
- Open communication with coordinator and administrator





Resources

- All form templates are found on UTHSC-H Office of Research website -
<http://www.uth.tmc.edu/ctrc/budgetdevelopment.html>
- UT Price List is found on UTHSC-H Office of Research website



References

- Center for Medicare and Medicaid.
- Fedor, Carol A. Responsible Research, A Guide for Coordinators. London, UK: Remedica, 2006.
- Schroeder, Pam, Allen, Esq., Mary Ellen, “Practical Payment Terms: Show Me the Money \$\$” 16th International Contracting & Negotiating Clinical Trials, Sept.19-21, 2005.
- Woodfin, Karen E. The CRC’s Guide to Coordinating Clinical Research. Boston, Mass: CenterWatch, 2004
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