

Class is meant to supplement other training, not as all inclusive training. This session will not be recorded, but this PowerPoint can found:

<https://medschool.ucla.edu/research/research-infrastructure/administrative-support/department-of-medicine-office-of-research/fund-management-training>

# Clinical Trials

## Post-Award: Invoicing & Ledger Reconciliation

UCLA DEPARTMENT OF MEDICINE  
OFFICE OF RESEARCH ADMINISTRATION  
ZOOM TRAINING

# Summary

- Invoice Sponsor
  - Generate an invoice to sponsor
  - Handle delayed sponsor payments
  - Best practice & tips
- Ledger reconciliation & management
  - Overview
  - Key Points
  - REFUEL March 2023 (patient care expense process)
  - Reconciling patient care
  - How to handle discrepancies
  - Allowable costs
  - Best practice & tips

# Overview

## CLINICAL TRIALS



# Overview

- An **invoice** is an itemized bill of items or services provided, containing unit prices, totals and payment terms, that serves as a request for payment.
  - Any billing errors should be identified once an invoice is remitted and prior to receiving payment
- **Cost reimbursements** - The department incurs expenditures and invoices the sponsor based on the payment schedule in the award agreement (usually either monthly or quarterly). These invoices are generally issued based on contract budget milestones.
- Note: It is important to submit timely invoices due to some contracts having *strict* payment terms including invoicing schedule
- Amounts invoiced to Industry (For-Profit) sponsors are **not the same** amounts indicated on general ledgers

# Invoice Management

CLINICAL TRIALS

# Invoicing

- Review contract for sponsor's invoicing guidelines and instructions. You can send an invoice by email or by mail
  - Note: Payment Terms also included on Summary sheet of Calc workbook
- When invoicing, you must also consider payment terms for:
  - Quarterly auto payments, which may mean no invoicing for patient visits only
  - Ratios / Caps (i.e. screen fails)
  - Holdback amounts/percentage
  - Final payments (items that need to be performed prior to invoicing)
- Common invoicing methods include:
  - Study Team submitting case report forms (CRFs) to sponsor or entering data into the sponsor's electronic case report forms (eCRFs) or database
  - Use of [Calc Template](#) for CT invoicing and tracking
  - Contract review for required information upon submission of invoice. (i.e. description of services provided (subject#, visit/invoiceable procedure, date of service, amount) or UCLA invoice # referenced on check submissions with PI name, Sponsor, protocol#, IRB#.

# Invoicing - FAQs

- Where can I find an invoice template?
  - [CT Invoice Sample](#) - Use template and insert contract payment information
  - Note: Some sponsors have their own invoicing portal/system. Request access as necessary.
- What is a [holdback](#)?
  - Sponsors may withhold a portion of the invoice as a specified amount/percentage until all the work is complete.
- Items in contract may indicate a [cap](#). Can invoices still be submitted if item exceeds cap?
  - Inquire with Study Team and request a written approval from Sponsor. If approved, send invoice with written approval.
- What do you do when [unscheduled visits/procedures](#) are completed but *not* currently contracted and PI is determined to bill-to-study?
  - Please submit a request to DOMCTP attention DOM Charge Reviewer via email, providing the following:
    - Provide subject name, date of service and PI and IRB# (retain from study team)
    - Inform CRBP office not to bill (*especially not the patient*) until the billing for this visit is determined



# Invoice Process

- Review payment terms re: invoiceable items on agreement
- Determine what can be invoiced by reviewing the [CT Calc workbook](#)
- Generate [CT Invoice](#)
- Tips:
  - Suggested invoice name/number for easy reference: Fund\_Inv# (ex. 81234\_1)
  - Update Financial Summaries to project earnings and note on receivables
  - Save & send invoice as PDF

UCLA		UCLA Department of Medicine Division of Administration INVOICE			
Sponsor's Protocol Number:				Invoice Date:	
Sponsor Site/Project Code:				Invoice Number:	
Sponsor:					
Sponsor Contact Name:					
Attention to (if applicable):					
UCLA Clinical Trial Fund Manager:					
Email:					
UCLA Fund Number:					
UCLA Investigator Name:					
IRB Number:					
Study Title:					
Item / Patient #	Description	Date(s) of Service	Unit Cost	QUANTITY	AMOUNT
Annual Committee Renewals	Continuing Review	2019, 2020		2	\$ -
Amendment with or with ICF: IRB/Protocol	Version 2	01/02/2020		1	\$ -
Subject #00000	Visit 1 / Screening	01/15/2020		1	\$ -
TOTAL AMOUNT BILLED					\$0
Send Payment To:			Make Check Payable To:		
The Regents of the University of California Payment Solutions & Compliance Box 957089, 1125 Murphy Hall 405 Hilgard Avenue Los Angeles, CA 90095-7089			The Regents of the University of California, Los Angeles		
Reference: INVOICE #			Federal Tax ID: 95-6006143		
PI NAME					



# Separate Invoice Process

Billing for professional services is important because it's how we get reimbursed for efforts performed on projects (even if they didn't reach contract execution)

- There are no payment terms/contract to review
- No [CT Calc workbook](#)
- Send email and generate a letter to sponsor for reimbursement prior to sending invoice
  - Example email: Available upon DOMCTP request
  - Example: [CT Start up Reimbursement Letter and Invoice Sample](#)
- Tips:
  - Save correspondence from sponsor to pay such costs.
  - Save Invoice & send as PDF

Insert Date

Insert Company Name ("Company")  
Insert Address

Subject: Intent to Reimburse for Study Startup Activities in the Absence of an Executed Clinical Trial/Study Agreement ("Reimbursement Letter")

Company's Study Protocol No: \_\_\_\_\_ ("Study")

Dear (Company Name) Official:

The Regents of the University of California, Los Angeles Campus ("Institution") has been actively engaged in Study startup activities for a Study in which the Institution was to serve as a Study site; however, the Institution and Company have decided not to proceed with activation of the Study at Institution's site.

Company acknowledges that the Institution has incurred fees and expenses as a result of engaging in necessary Study startup activities and as such, Company agrees to reimburse Institution a non-refundable payment for Study startup activities as invoiced to Company by Institution, such invoiced amount not to exceed \$ \_\_\_\_\_. To receive reimbursement, Institution will submit an invoice to Company for fees and expenses incurred.

Company will pay such amount as set forth in the invoice from Institution no later than thirty (30) days after Company's receipt of the invoice.

Payments will be made payable to: The Regents University of California, Los Angeles

Payments will be mailed to:  
UCLA Payment Solutions & Compliance  
Box 957089, 1125 Murphy Hall  
405 Hilgard Avenue  
Los Angeles, CA 90095-9000

All payments will be made in United States dollars by check and will reference the invoice number \_\_\_\_\_, Company name, UCLA Investigator last name \_\_\_\_\_ and Study protocol number \_\_\_\_\_.

By signing below, the Company acknowledges acceptance of the terms of this Reimbursement Letter.

ACCEPTED AND AGREED TO:

# Invoicing

- Invoices must be **HIPPA-compliant**
  - Be sure to *remove* any patient information on documents sent to sponsor, including supporting documents for invoices
  - Do *not* include subject/patient/personal information (MRN, name, address, phone, etc.). It is acceptable to use subject ID#.
  - If there is a HIPPA violation, be sure to inform your supervisor immediately, contact PI and seek further instruction by UCLA's IRB

# Delayed Sponsor Payments

CLINICAL TRIALS

# How to Handle Delayed Sponsor Payments

- Sponsors usually take around 1-2 months to review, approve and process invoices so the payment process may take 2-4 months to receive payment to appropriate FAU.
  - Sponsor will cut check ~1-2 weeks after approval and as indicated terms on contract, then mail out to UCLA
- If payment appears to be delayed:
  - Follow up with sponsor and request payment details (i.e. payment/check #, date issued, and itemized breakdown) from sponsor
  - Follow up with EFM to track payment with payment details provided by sponsor
    - Tip: Request a copy of check (front/back) from sponsor for best tracking. It contains check details including address (sometimes payments are mailed to a different UCLA campus/dept).



# How to Handle Delayed Sponsor Payments

- At times sponsor may indicate a correction in invoice to be made, you may add or remove items invoiced based on feedback from study team confirming they agree with sponsor.
- If sponsor is unable to resolve payment issues or become unresponsive. Which path should I take?
  - 1<sup>st</sup> attempt- contact Study Team for additional sponsor contacts (i.e. Project Lead)
  - 2<sup>nd</sup> attempt - inform PI and request PI's primary sponsor contact
  - 3<sup>rd</sup> attempt - involve all sponsor contacts and include previous email correspondences with trailing dates
  - 4<sup>th</sup> attempt - escalate to the appropriate Contract Office
    - Consult with your contract officer prior to getting them involved in writing. May ultimately go into legal matters.

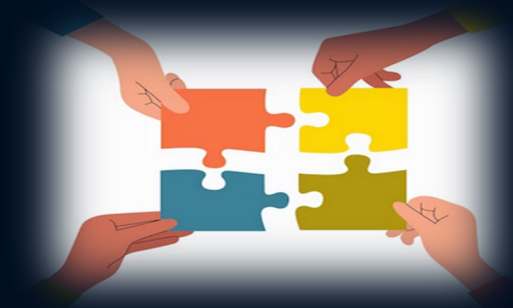


# Common Misconceptions

- Sponsor/CRO pay on time and accurately pay for work performed
  - *FALSE* – these payments are rarely paid “on-time” per the contract payment terms
- Once invoices are submitted, they are paid timely and accurately
  - *FALSE* – invoices often need to be resubmitted because they were lost or never received
  - *FALSE* – invoices can have inadequate supporting data, incomplete CRFs or unresolved queries
- Patient payments are paid correctly
  - *FALSE* – unfortunately there are more discrepancies than properly paid payments. Items within a visit are often short-paid, sponsor lacks CRF data to make payment, or sponsor make errors in payments

# Best Practice & Tips

- Clinical research site payment issues often occur so it is very important to maintain account receivables and follow up regularly with sponsor. The study team may even decide to stop working with sponsors if payment issues persist.
- Sponsors, CROs and UCLA, all must join hands to collaborate and find a practical, transparent and all-inclusive solution that streamlines payment processes for sites in order to:
  - Speed invoicing time
  - Prevent missed items
  - Reduce payment delays for work completed
  - Ensure you're receiving what you're owed
- Tips:
  - Follow-up is key when receiving timely payments whether performed with sponsor or internal follow-up to study team.
  - For electronic payments (EFT /ACH), refer to [UCLA Biz & Finance Solutions- Dept EFT Payments](#)



# Ledger Reconciliation & Management

CLINICAL TRIALS



# Overview

- The **General Ledger (GL)** is the record of all accounts used by UCLA. It is the main accounting record, containing and recording every accounting transaction.
- **General Ledger reconciliation** is an internal control procedure that helps ensure account balances in the general ledger are materially correct. This process must be carried out in a timely and consistent manner at the same time each month for optimal efficiency.
- For clinical trials, patient care related expenses are found on the GL and need to be reconciled
  - Once the monthly ledger becomes available and monthly statements are ran for the study FAU, the ledgers should be reconciled and appropriate back-up documentation obtained.

# Key Points

## Understand the terms and contents of the account

- Knowing what transactions belong in the account will be extremely helpful as you proceed. For example, if you are reconciling a clinical trial account, you will need to understand which items are appropriate/research-related based on the contract
- Gather supporting documentation for the account. When performing ledger reconciliation, you will need items including invoices/receipts, service logs, and other supporting documentation.
- Expenses hitting the ledger should accurately reflect *approved* charges
- Any unusual transactions (i.e. large amounts, unrecognized source) should be addressed promptly

# Patient Billing

- Clinical Trials will incur **patient care and related expenses**, such as hospital/professional billing, subject reimbursements, pathology/lab services and pharmacy.
- **The following process takes place prior to hitting our General Ledgers. This is not a Fund Manager responsibility as the Approvals for charges on patient care related items are centralized.**
  - Research Billing Refuel increased transparency in tracking research-related charges within CareConnect. A number of tools have been implemented to view Hospital Billing (HB) and Professional Billing (PB) charges for studies.
  - A two Tier Process
    - Tier 1 – DOM Charge Reviewer/Study Team are responsible for approving charges that are reviewed in the Care Connect dashboard queue by using OnCore or working with each other to confirm. Afterward, the charges are directed to Bill to Study, Study Related – Bill to Patient, Non-Study.
    - Tier 2 – CRBP unit will also review as a double check charges already approved by Tier 1 and address hiccups as necessary.

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# Patient Billing – Best Practices

- Charges are reviewed daily and new charges drop every 3-4 hours in the dashboard queue. DOM has 7 business/10 calendar days which include weekends to complete. After, Tier 2 has the same timeline.
- All charges on Dashboard are reviewed timely. Both DOM and CRBP work together to assure timely approvals.
- Best Practices -
  - Concern about incorrect billing, contact [DOMCTP](#). DOM Charge Reviewer will get appropriate contacts involved to correct billing.
    - A Request to CRBP to place a freeze on further collections.
    - Check with Study Team to assure Linking of study account/Insurance.  
“Without linking there will be no trigger for billing review”
    - Reimbursement to Insurance/study account may occur.
    - Study Team to confirm with patient once billing is corrected.

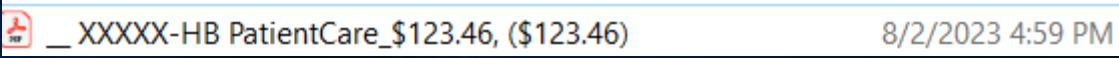
# General Ledger - Billing Reconciliation

- Why is it necessary for department-level reconciliation?
  - Departments know first hand on what occurs during the life of a project
  - Coding and billing for clinical trial services are complex and at times subject to errors between with physicians, practices, facilities and all other involved parties. It is necessary to reconcile for the purpose of approving costs to be appropriately reflected on ledgers. Common issues include:
    - Result of loss of income
    - Billing errors (wrong amount, charge not study related or contracted)
- What does reconciliation consist of?
  - Run monthly GL statements
  - File copies of supporting documentation or departmental
  - accounting records
  - Review expenses and compare to back-up
  - Locate discrepancies and correct as needed



# General Ledger - Billing Reconciliation

Doing a ledger reconciliation means Fund Manager will need to compare each transaction on ledger with its corresponding transaction on your back up documentation. Patient Care expenses tied to the ledger are usually indicated by [object codes 3456/3466](#).

- Open your already ran ledgers stored in the Financial Statements Folder. using tab "CLOSED -XXXXXX-XX-XXXXX".
- Review Patient Care expenses hitting Sub 03 Patient Care ([Financial Statements](#)).
- [Date and initial](#) your review on ledger using [GL Compliance](#) instruction. Also note any discrepancies, corrections and additional memos.
- Use the [CT Common Expenses and Contacts by Object Code](#) to retain any other ancillary back up for reconciliation.
- Effective March 2023 Patient Care Back-up is already stored at your convenience in the DOM Fund Managers Odata drive divisional folders ([O:\Funds\Division- name\\\_#\\\_PatientCare\\_Back-up](#)).
  - Folders should be organized by [Fiscal Year](#) then [Month](#) (similar to monthly statements)
  - Example naming convention 
- If you do not have the back-up in your files, refer to CT Contacts List by Object Codes to identify contacts to request for appropriate patient care back-up

# General Ledger - Billing Reconciliation Completed

GL: XXXXXX-XX-XXXXX SUB:03,04,05,07,08,09 FOR JUNE 2023 Date: 07/18/2023																		
Sub	Trans Ref GL	Ledger Year Month	Project	Object	Account	CC	Fund	Sub-Object Title	Source Code	TE	Trans ID GL	Trans Doc Date	Trans. Eff. Date	Description	Expense			
03		202306		4730	XXXXXX	XX	XXXXX	PHARMACEUTICALS		59	123155	7/1/23	6/30/2023	40064	55.00			
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/10/23	6/1/2023	23671029000000000000	123.46	x		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/10/23	6/1/2023	23671029000000000000	(123.46)	07/31/23 system glitch, correction.		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/10/23	6/1/2023	23671029000000000000	(123.46)	07/31/23 system glitch, correction.		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/10/23	6/1/2023	23671029000000000000	(123.46)	07/31/23 system glitch, correction.		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/10/23	6/1/2023	23671029000000000000	(123.46)	07/31/23 system glitch, correction.		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/24/23	6/3/2023	23706207000000000000	125.77	x		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/24/23	6/3/2023	94027300000000000000	9.52	x		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	11871	5/31/23	6/4/2023	23736156000000000000	8.57	x		
03	XX-XXXXXX	202306		3466	XXXXXX	XX	XXXXX	PATIENT CARE(EXCLUDED FROM O		59	12871	6/7/23	6/6/2023	23765822000000000000	14.69	x		
03	JUN2023	202306		4440	XXXXXX	XX	XXXXX	DEPARTMENTAL STORES AND SUP		59	124386	7/7/23	6/30/2023	DRY ICE	9.84	x		
Sub 03															(146.99)			
Sub Grand Total															(146.99)			



# Back up for patient care expense

- Example of EPIC Back up to expense that is reflected on ledger
- Example of Credit/adjustment back up for same expense reflected on ledger

Charges

Group by: Revenue Code CPT®/HCPCS Code Svc Date Svc Date - Px Patient

Total (2)  
123.46

Select All Deselect All Filters

Export

Patient	Description	Qty	Total Amount
<input checked="" type="checkbox"/> Subject Information [REDACTED]		5	[REDACTED] Amount

Itemized Charges

Action Select All Deselect All

Export

Svc Date	Post Date	Procedure	Rev Code	Modifier	Qty	Amount
<input checked="" type="checkbox"/> 04/13/2023	04/14/2023	[REDACTED] HB RSH SAMPLE COLLECTION & HANDLING	[REDACTED] LABORATORY - GENERAL CLASSIFICAT...	—	1	[REDACTED] Amount
<input checked="" type="checkbox"/> 04/13/2023	04/14/2023	[REDACTED] HB RSH OUTPATIENT ROOM PER 30 MINS	0490- AMBULATORY SURGICAL CARE - GENERAL CLASSIFICAT...	—	4	[REDACTED] Amount

Payments and Refunds

Select All Deselect All Filters

Export

Total (1)  
-123.46

Dep Date	Post Date	Procedure	Payer	Source	Amount
<input checked="" type="checkbox"/> 05/09/2023	05/09/2023	[REDACTED] HB RESEARCH STUDY RECHARGE PMT	— IRB#	UC Recharge [REDACTED]	-123.46

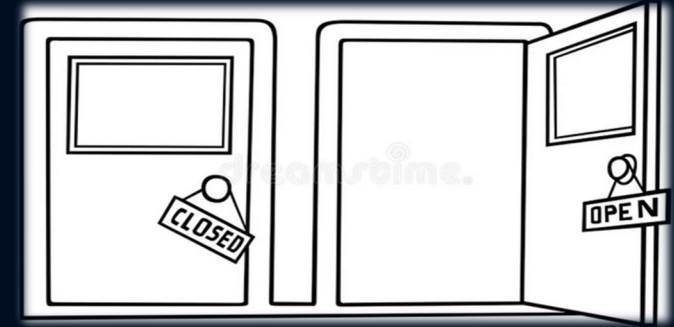
Adjustments

# Allowable Costs

- An **allowable cost** is a cost that can be paid by your contract or grant and must be:
  - **Reasonable** - A cost may be considered reasonable if the nature of the goods or services and the amount of cost involved reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made
  - **Allocable to the project** - A cost is allocable to a sponsored project if (1) it is incurred solely to advance the work under the sponsored agreement or (2) it benefits both the sponsored project and other work of the institution in proportions that can be approximated through use of reasonable methods
  - **Necessary** for the project

# Allowable Costs

- Also, **allowable costs** are:
  - Treated consistently for all applicable work
  - Compliant with sponsor and award restrictions, limitations, or exclusions
  - Contract should have specific provisions and procedures considered billing prior to the patient joining study. If these provisions do not exist in the original agreement, an amendment to the contract is necessary.
  - Incurred during the project period
  - Adequately documented
  - Not charged elsewhere (no double-charging)
  - Charges that should be hitting account at the actual cost rate (non profit). The budget in the contract is the only amount we should be invoicing for.



# Discrepancies & Issues

- A critical element of the reconciliation process is resolving any discrepancies, which should be identified, investigated and corrected or justified.
- Corrective action is necessary to maximize earnings and ensure appropriate expenses are applicable to the study.
- **Unallowable** /Common discrepancies/issues include:
  - Duplicate Billing identified, you must contact the servicing department to credit your account emailing both charges.
  - Erroneous billing identified and does not belong to the account, you must contact the servicing department to remove charge.
  - Incorrectly billing found and is for another account, the approver should request a correcting expense transfer or complete a NPEAR with the associated back-up.
- The reconciler should then **ensure that the correcting entry is posted accordingly.**



# Important to Know

- *Items that hit your ledger*
- Should match the Charge Master according to the rate in effect at the time of pre-award.
- Should **not** be the same amount on your contracted budget in most cases. Your budget amount is typically more than what's hitting your ledger since in the budget standard inflation is considered during pre-award.
- For non profit budgets, Fund Managers should evaluate if sponsor approval is required to re-budget (or renegotiate) to accommodate inflated costs which do not align with the sponsor-approved budget (e.g. NIH GPS 8.1.2.5 outlines re-budgeting into and out of Patient Care Costs may constitute a change in scope)

# Important to Know



- *Items which are reviewed and approved*
- Fund Managers must retain the back to reconcile the General Ledger patient care/procedures, and ensure all costs approved “Bill to Study” by the Patient Billing Department ultimately drop to the General Ledger, Expense.
- Fund Managers are additionally responsible for ensuring that all studies on a Fixed billing structure (as opposed to cost-reimbursement) are up-to-date with Sponsor Invoicing. Invoices to sponsors must be developed according to the contracted, approved budget. Sponsor Payments must ultimately drop to the General Ledger, Appropriation.

# Best Practices & Tips

- Reconciliation provides help with control activity to ensure the accuracy and completeness of transactions that have been charged to a department's accounts.
- Project codes, Source Codes are used to identify a specific project, program or group of activities intended to be financially tracked. This method can be used to identify expenses easier.
- Save in your files any documents that are approved for funding from your sponsors for items not currently in the contract. You will use this later to help you reconcile.
- Work with study team to obtain some of the back-up for ledgers. Some items do not autogenerate back-up documents (like invoices or service request forms) so they require manual supporting documents such as item/service tracking logs (i.e. [CT Dry Ice Log Template](#) and [CT Subject Parking Log Template](#))

# Links from Today's Class

- DOM Clinical Trials Fund Manager Manual Chapters
  - [CT Invoice Sample](#)
  - [CT Contacts List by Object Codes](#)
- Clinical Trial Contacts
  - [Clinical Research Business Partners \(CRBP\)](#)  
(UCLAHSCRBP@mednet.ucla.edu)
  - [DOM CTP](#)



# Survey Link

<https://forms.gle/QaMyquTmKtNDEj1k8>

We appreciate if you would take a few moments to complete a short 7 question anonymous survey to help us improve your training experience. Thank you!