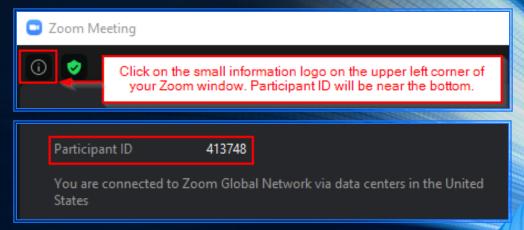
If you do not have a microphone on your computer, or using remote desktop to join this meeting, please also call in to participate in class discussions:

Call one of the "Join by Telephone" dial-in number provided in your invite (646-876-9923).

Enter the Meeting ID (968 5919 6077) followed by #.

Enter your Participant ID followed by #.

This session will *not* be recorded, but this PowerPoint can found https://medschool.ucla.edu/ora/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
 - Research Transaction Reports (RTR) prior to hitting General Ledgers
 - Quick guide to reconciling Clinical Trial ledgers
 - 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

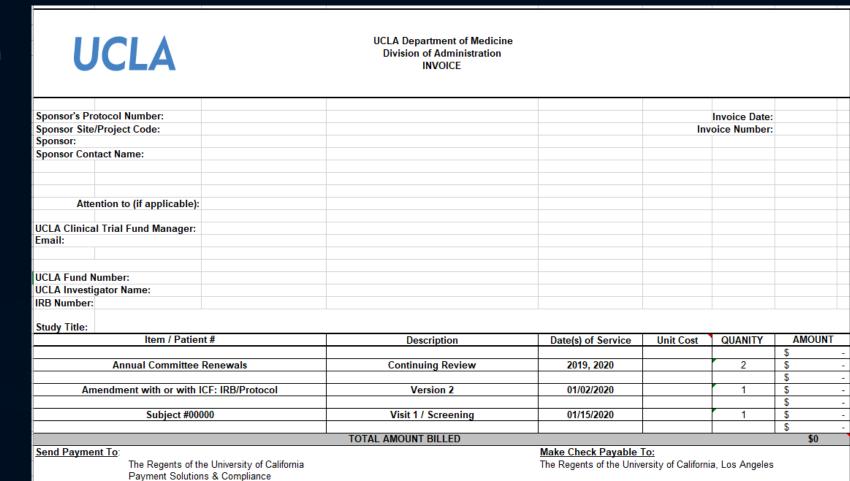
- Review contract for sponsor's invoicing guidelines and instructions. You can send an invoice by email or by mail
 - Note: Payment Terms also included on Summary sheet of Calc workbook
- When invoicing, you must also consider payment terms for:
 - Quarterly auto payments, which may mean no invoicing 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 <u>Calc Template</u> 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?
 - <u>CT Invoice Sample</u> 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?
 - Send request for visit detail to <u>Clinical Research Business Partners (CRBP)</u>
 - 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

Invoicing

- Review payment terms re: invoiceable items on agreement
- Determine what can be invoiced by reviewing the <u>CT Calc</u> workbook
- Generate <u>CT Invoice</u>
- 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



Box 957089, 1125 Murphy Hall

Los Angeles, CA 90095-7089

405 Hilgard Avenue

INVOICE #

PI NAME

Reference:

Federal Tax ID: 95-6006143

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..
 - 1st attempt- contact Study Team for additional sponsor contacts (i.e. Project Lead)
 - 2nd attempt inform PI and request PI's primary sponsor contact
 - 3rd attempt involve all sponsor contacts and include previous email correspondences with trailing dates
 - 4th 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 <u>UCLA Biz & Finance Solutions- Dept EFT Payments</u>

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 αpproved charges
- Any unusual transactions (i.e. large amounts, unrecognized source) should be addressed promptly

Patient Billing - Reconciliation

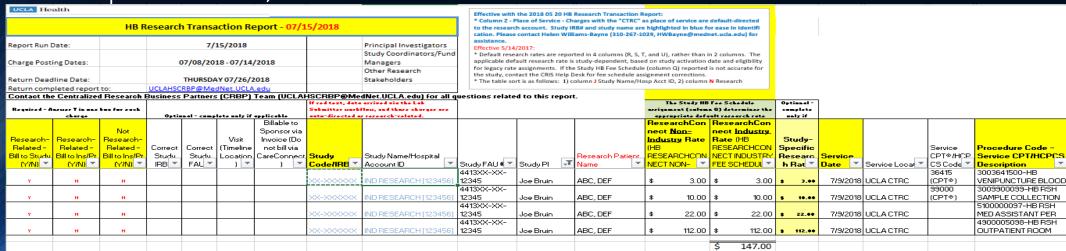
- Clinical Trials will incur patient care and related expenses, such as hospital/professional billing, subject reimbursements, pathology/lab services and pharmacy.
- The following process takes place prior to hitting our General Ledgers.
 - Every week CRBP will send study teams a Hospital Billing (HB) and/or a Professional Billing (PB) Research Transaction Report. Both reports are directed to designated study contacts for review and validation of each pertinent charge.
 - Charge Reviewer/Study Team/Fund Manager are responsible for notifying CRBP if charges should be directed to the patient's guarantor account rather than the study account.
 - Patient Care procedure items are reviewed during Research Transaction Report (RTR) submitted by our Patient Billing Department. Charge Reviewer/Study Team/Fund Manager should use the contract budget to reassure items are research related and if charge should be billed-to-study or billed-topatient/insurance.

Patient Billing - Reconciliation

- Research Transaction Reports (RTR) is hospital and professional billing that consists of excel spreadsheets and sent to the serviced department for approval to charge study or subject/Insurance for procedures that were performed.
- All charges on the RTR should be reviewed timely and approved by the Charge Reviewer/Study Team/Fund Manager to ensure appropriate study charges.
 - If you are not receiving on weekly RTRs from the UCLA Centralized Research Business Partners (CRBP) team, email UCLAHSCRBP@mednet.ucla.edu and request to be added to the distribution list
 - Coordinate with your Study Team to ensure everyone is copied on the approved RTR sent back to CRBP

Patient Billing - Reconciliation

- Getting Started on RTR Approval Process you'll need to have handy
 - Oncore Subject Visit Procedure Report
 - Budget
- Perform the following to determine approval for each charge once you receive the RTR
 - Filter Report by PI, per IRB/study FAU
 - 2. 1st 3 columns, Research Related Bill to Study, Research Related Bill to Insurance, Not Research Related bill to Insurance. This is all confirmed by the Study Team
 - 3. Go into Oncore to run Procedure Report to determine which study visit this charge was for
 - 4. Confirm rate of Research Connect Industry Rate cell (reference Charge Master Rates using CPT provided in RTR)



- 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

- Review Patient Care expenses hitting Sub 03.
- Insert an additional column to date and initial your review on ledger. Also note any discrepancies, corrections and additional memos.

\square	Α	В	С	D	Е	F	G	Н	I	J	K	L	M	N	0	P	Q	R
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			Ledger Year							Source		Trans ID	T	Trans. Eff.				
2	Sub			Project	Object	Account		Fund		Code	TE		Doc Date		Description	Expense	LC 07/15/21	
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5				-			_					103431			_			
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6	03		201904		4730	4413XX	XX	12345	PHARMACEUTICALS			103503	5/1/19	4/30/2019	25635	500.00	X	Duplicate charge
7	03		201905	ľ	4730	4413XX	XX	12345	PHARMACEUTICALS		59	110398	5/2/19	5/2/2019	25635	(500.00)	X	correction, charged in error
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8	03	1900XWA378	201810	CHAYO1	3355	4413XX	XX	12345	HUMAN SUBJECTS			137079	10/1/18	10/15/2018	CHAYOT, SHI1560XWA	200.00	Χ	Purchaser/Fund Mgr
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10	03	17-001408	201808		3456	4413XX	ХX	12345	PROFESSIONAL SERVI		59	023331	9/7/18	8/31/2018	CPRS SVC-AUG 18	85.00		request 07/15/22
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							7	•										Approved \$730 difference, no
																		notification to FM. Spoke to
																		CRBP, Michelle McDaniel
12	03	17-001408	201810	10H18R	3466	4413XX	XX	12345	PATIENT CARE(EXCLU	072918	59	041969	10/26/18	10/26/2018	HB RR CTRC	727.00	X	adjustment made
13	03	17-001408	201810	10H18R	3466	4413XX	XX	12345	PATIENT CARE(EXCLUI	082618	59	042392	10/30/18	10/30/2018	HB RR CTRC	56.00	X	
14	03	549636	201810		3464	4413XX	XX	12345	PARKING SERVICES (R		54	040453	8/1/18	10/17/2018	59029003S-7/9 RESER	12.00	Χ	RBX04-001 wk 1 visit
15	08		201804		3456	4413XX			PROFESSIONAL SERVI			100227	4/6/18		CT IRB FEE-Bruin	2,500.00		IRB Mandatory UCLA Fee -
							-		aarch Administrat				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			3,700.00		

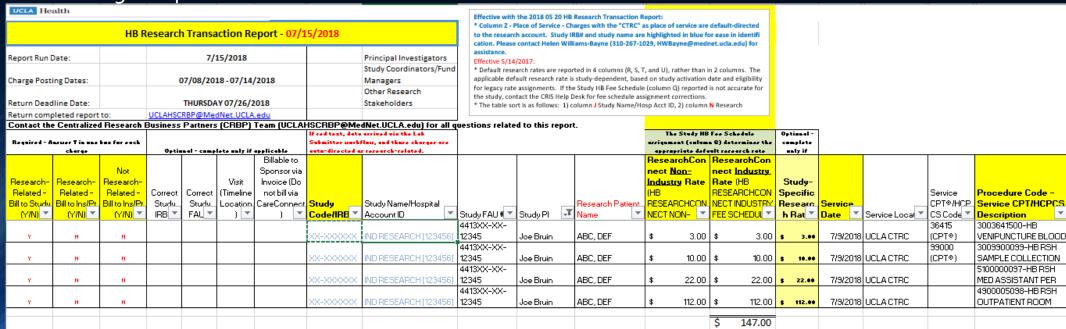
- Patient Care expenses tied to a Research Transaction Report (RTR) are usually indicated by object codes 3456/3466 and 6 digit source code (MMDDYY).
 - If you do not have the back-up in your files, refer to CT Contacts List by Object Codes to identify contacts to request for appropriate patient care back-up

4	4	Α	В	С	D	E	F	G	Н	I	J	K	L	М	N	0	P	Q	R
1	GL: 4413XX-XX-12345 SINCE FEBRUARY 2021(ITD) Date: 06/30/2021																		
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2	5	òub	GL	Month	Project	Object	Account	CC	Fund	Sub-Object Title	Code	TE	ID GL	Doc Date	Date	Description	Expense	LC 07/15/21	
1:	1	03	XX-000000	201810	10H18R	3466	4413XX	XX	12345	PATIENT CARE(EXCLUDED)	071518	59	041697	10/23/18	10/23/2018	HB RR CTRC	147.00	Χ	
									,										Approved \$730 difference, no notification to FM. Spoke to CRBP, Michelle McDaniel
17	2	03	XX-000000	201810	10H18R	3466	4413XX	XX	12345	PATIENT CARE(EXCLUDED)	072918	59	041969	10/26/18	10/26/2018	HB RR CTRC	727.00	X	adjustment made. 07/15/21
1.	3	03	XX-000000	201810	10H18R	3466	4413XX	XX	12345	PATIENT CARE(EXCLUDED	082618	59	042392	10/30/18	10/30/2018	HB RR CTRC	56.00	X	

Example: Source code (MMDDYY): 071518 and description (type of RTR): HB and expense: \$147.00

Source Code	TE	Trans ID GL	Trans Doc Date	Trans. Eff. Date	Description	Expense	LC 07/15/21
071518	59	041697	10/23/18	10/23/2018	HB RR CTRC	147.00	X

- 1. Open appropriate RTR (HB vs PB) report (file named by date HB 2021 07 15)
- Filter by Study Code/IRB (column I)
- 3. Sum/total all rates under Research Connect Industry Rate (column U) to reconcile with ledger expense amount



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/non-profit rate. 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 <u>Charge Master</u> according to the rate in effect at the time of preaward.
- 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 rebudgeting 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 use the RTR 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.
- DOM Fund Managers MUST file approved RTRs in O drive divisional folders (O:\Funds\Division—name_ResearchTransactionReport (RTR)).
 - Folders should be organized by Fiscal Year then Month (similar to monthly statements)

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. <u>CT Dry Ice Log Template</u> and <u>CT Subject Parking Log Template</u>)

Links from Today's Class

- DOM Clinical Trials Fund Manager Manual Chapters
 - <u>CT Calc Template</u>
 - CT Invoice Sample
 - CT Contacts List by Object Codes
 - CT Dry Ice Log Template
 - CT Subject Parking Log Template
- Clinical Trial Contacts
 - Clinical Research Business Partners (CRBP)
 (UCLAHSCRBP@mednet.ucla.edu)
 - DOM CTP (DOMCTP@mednet.ucla.edu)

Survey Link https://forms.gle/QaMyquTmKtNDEj1k8

We appreciate if you would take a few moments to complete a short 5 question anonymous survey to help us improve your training experience. Thank you!