

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 Budgeted Costs

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Summary

- Understanding the Cost List
- Determining Study Team salaries
- Ancillary recharges
- Hard vs Soft costs
- Non-Profit vs For-Profit (Industry) rates
- Review & FAQ

Overview

- Most clinical trials conducted in the United States are funded either by the federal government (particularly the National Institutes of Health) or by private drug and device companies
 - In these clinical trials, it is unusual for the sponsor, institution, or investigators to ask subjects to bear costs *beyond* those associated with **routine care**. Subjects generally participate without being charged for research interventions and associated care, and conversely, are often reimbursed for study-related expenses, offered compensation for time and burden, and/or paid incentives to encourage enrollment and retention.
- UCLA DOM provides an **infrastructure** for managing clinical trials
 - Stakeholders involved include clinical, regulatory, financial and administrative staff as well as servicing departments/ancillaries, contract offices, etc.

Overview

For **Clinical Trial Costs**, it is important to understand...

- How costs are negotiated and determined in budgets by various stakeholders
- What Cost List items (administrative vs procedure costs) are being included in budgets
- What costs are applicable to Study Team salaries vs Ancillary/Dept recharges vs 3rd party expenses
- Use of CPT codes for Hard (vs Soft) costs
- The Non-Profit Rates vs Industry (For-Profit) rates within a Cost List

Research Administrators are not responsible for creating budgets & costs but it is helpful to understand how they are established for financial management, including budgeting and invoicing.

CT Key Terminology

- **Ancillary** – Servicing department who provides necessary support to the primary activities or operation of clinical trials.
- **Centers for Medicare & Medicaid Services (CMS)** - A federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards.
- **Current Procedural Terminology (CPT)** - National uniform billing grouped items so that they are identified numerically. Medical code set that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations.
- **RC₁** - Billing determination that is used as a Routine Cost indicator for patient care budgets (RC₁ = Bill to Pt/Insurance, Q1 billing modifier, Routine Cost)
- **Standard of Care (SOC)** – a diagnostic and treatment process that a clinician should follow for a certain type of patient, illness or clinical circumstance

Cost List

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Cost List

- A Cost List (rate schedule) is used for cost determination of negotiated budgets and invoices
- The goal in using a Cost List is to standardize department rates to negotiate for Industry (For-Profit) sponsored contracts and to reduce the difference in cost estimates
 - Tip: Contact [DOM CTP](#) for DOM approved Cost List
- Most billing systems were not constructed with research in mind, therefore a Cost List is necessary




Cost List

- Various teams work together to determine the appropriate methodology for aggregating the itemized costs that characterize the overall cost of a clinical trial including:
 - Patient recruitment & retention costs
 - Clinical research staff & procedural costs
 - Laboratory or specialty department costs
 - Sub-Site recruitment & retention costs
 - Administrative costs including renewals, closures, etc.
- There are several **factors** on how Clinical Trials Costs are negotiated and determined
 - Factors considered include study size (number of patients), locations (clinic/practice), number of clinical sites, therapeutic area, drug type, and the specific tests and procedures needed per protocol, and more

DOM Clinical Trials - Cost List

- It is updated annually as a result to CMS updates Medicare prospective payment systems every year
- It also is updated throughout the year to include items/procedures that are most commonly performed
- It consists of:
 - CPT Code(s)Item/Descriptions
 - Non-Profit Rates (actual Costs)
 - Industry Rates (minimum used on for-profit)
 - Department Rates (for-profit)
 - Indirect Costs (includes Industry UCLA overhead (F&A))
 - Total Costs

The Cost List is maintained by DOM CTP.

 David Geffen School of Medicine Department of Medicine						
UCLA MISCELLANEOUS:--Payment will only be requested if additional procedures are required beyond those of the per patient budgets or that are not						
CPT CODE	ITEM	Non-Profit Rates (Charge Master)	Industry (Charge Master)	Rates	INDIRECT COSTS	TOTAL COSTS
Procedures/Assessments						
	Informed Consent			-	0	0
99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99245, G0463	Office Visit/Physical Exam/TeleHealth	0	0	-	0	0
	Performance Status (ECOG)	X	X	X	X	X
	Adverse Events	X	X	X	X	X
	Conmeds	X	X	X	X	X
	Vital Signs	X	X	X	X	X
	Extensive Vital signs	X	X	-	0	0
	Weight	X	X	X	X	X
	Height	X	X	X	X	X
94760, 94761	Pulse Ox	0	0	-	0	0
46600	Endoscopy	0	0	-	0	0
36511, 36512, 36513, 36514	Leukapheresis Procedure	0	0	-	0	0

Costs

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Cost Classification

A Cost List is a classification or grouping of similar or related costs for purposes of reporting, determination of cost limitations and rates

- **Fixed Cost**
 - Does not change with an increase or decrease in the amount of goods/services produced
- **Direct Cost**
 - Directly accountable to the production of specific goods/services
- **Indirect Cost**
 - Not directly accountable to a specific cost object and often include UCLA overhead expenses
- **Total Cost**
 - The sum of direct costs and indirect costs

UCLA Non-Refundable Fixed Start-Up Fee			
ITEM	DIRECT COSTS	INDIRECT COSTS	TOTAL COSTS
Study Approval Process: Application Preparation & Submission to: IRB, ISPRC, MRSC, CA and Pharmacy	7,500	2,475	9,975
Mandatory UCLA IRB Submission Fee	2,500		2,500
Respiratory Set- up	2,000	660	2,660
Pharmacy PI Initiated Set-up Fee	1,500	495	1,995
CTSI Set-Up	500	165	665
Pathology and Laboratory Medicine Set-Up Fee	1,000	330	1,330
Upfront Payment Study Supplies (Printer, Binders, paper, folders, specimen vials etc)	3,500	1,155	4,655

Cost Types & Determination



- In addition to budgeted/negotiated costs, there are **Required Costs** (*non-negotiable* and *non-refundable* fees applicable to all sponsored clinical trials)
- Required Costs include:
 - Study Team Costs - items that are built into the budget for salaries/time & effort
 - Ex. Site Initiation Visit
 - Ancillary Costs - items charged by servicing departments
 - Ex. CTSI Remote Monitoring setup fee
 - UCLA Overhead/Indirect Costs - fees mandated by UCLA policies
 - Ex. Facilities and Administrative Costs (F&A)

Cost Types & Determinations

What are the 3 common types of costs on your budget and how are they determined?

1. **Research Study Related Costs** (Bill-to-Study)

- Research specific procedures would probably not be performed if the patient were not on a study
- Research specific procedures cannot be billed insurance for any item that is reimbursed by sponsor

2. **Routine Cost Billed to Insurance with Q1 modifier (Rc1)** (Research related / Bill-to-Patient)

- PI and study coordinator must carefully identify usual and customary care procedures vs. research specific procedures
- Usual and customary care procedures would probably be performed if the patient were not on the study
- Routine care tests and results may be used for research

3. **Standard of Care (SOC)** (not Research related / Insurance)

- Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.

Cost Types & Determinations

- What is the difference between **Research** vs **Routine (RC₁)** vs **Standard of Care (SOC)** costs?
 - The line can sometimes be unclear so it is important to understand *how* these costs are determined
- Stakeholders will determine actual costs as **Research related**, **RC₁** and **SOC** prior to finalizing budget. Meetings are held between UCLA and Sponsors to discuss budgeted costs for each unique protocol which then get built into the **Budget Calendar**.
- When compliance is met Charge Reviewers/Study Team/Research Administrator will use Budget Calendar to **avoid** the incorrect charge designation such as billing patient/insurance for:
 - Services already paid for by the sponsor (double billing)
 - Services promised free in the informed consent
 - Services that are for research only that are not allowable to bill Insurance



Cost Types & Determinations

- The **Cost List** may be used to aid with invoicing
 - Payments should be based on work conducted and the specific items and/or services rendered as listed in the Clinical Trial Agreement (CTA), including the budget.
- There are **miscellaneous costs** that do not reflect an amount on contracts/budgets such as:
 - **Subject reimbursable costs**, such as travel and lodging, may be anticipated and budgeted. The terms “actual cost plus UCLA overhead” means once the subject provides the receipts for reimbursement to UCLA, you can calculate the total cost including UCLA overhead to invoice to sponsor
 - Tip: terms such as “**billed at actual plus UCLA overhead**” may indicate as a reimbursable items in the contract
 - For **3rd Party costs** (i.e. Translation fee for Informed Consent Form (ICF)), the actual cost and UCLA overhead is presented to sponsor. This means once the vendor provides the invoice for payment, you can calculate the total cost including UCLA overhead to invoice to sponsor

Study Team Salaries

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Salary Related Costs

- Why aren't *actual* hourly rates/salaries used in budgeting for Clinical Trials?
 - Various staff are involved in making the clinical trial a success, including the research team (coordinators, assistants, students) and clinical staff
 - For Industry (For-Profit) studies salary related fees are not budgeted at hourly rates but on a per visit amounts
 - For Non-Profit studies salary related fees are budgeted using current payroll
- It is important to know what items are salary related costs to calculate and project available amounts, which is the goal/purpose of a [CT Calc Sheet](#)

Salary Related Costs – Industry/For-Profit

- On an **Industry/For-Profit budget** the applicable Study Team common titles/positions may include:

- PI / Co-I
- Study Coordinator
- Regulatory Coordinator
- Data Manager
- Research Assistant

- Usually specified on per subject items/costs
- The study team costs listed by title/positions determine the amount for reimbursement

Protocol Version: 1	
ARM ABC	Screen Day -14 to 1
Staff Cost	
Principal Investigator	\$ 2,500
Study Coordinator	\$ 1,500
Data Manager	\$ 900

Salary Related Costs – Non-Profit

- On a **Non-Profit budget** the common Study Team titles/positions may include:

- PI
- Co-PI
- Project Manager
- Lab Tech
- Study Coordinator

Project:	Protocol123							
PI:	Bruin, Joe							
Period:	07/01/20-06/30/22							
Inflation Factor:						1.00000		
						08/15/20-06/30/21		
						YEAR 01		
PERSONNEL:	Role	Base	EB	Eft	Salary	FB	Total	
Bruin, Joe	PI	150,000	0.300	1.0%	2,000	600	2,600	
Bruin, Jane	Study Coordinator	25,000	0.600	9.0%	3,000	1,800	4,800	
TOTAL PERSONNEL				10.0%	5,000	2,400	7,400	

- Usually specified on annual basis
- The study team costs listed by title/positions determine the amount that is paid upfront. No invoicing is necessary by DOM Research Administrator

Salary Related Costs – “Administrative” Fees

- Additional **Administrative** Salary Related Costs include:
 - Non-refundable start-up fees and invoiceable IRB costs
 - Study staff time & effort for visits and procedures (amendments, overtime, unscheduled visits)
 - *Refer to comprehensive list of [CT Industry Budget – Invoiceable Salary Related Costs](#)*
 - This variation may not be included on a non-profit budget to this extent
 - Most non-profit cost distinctions are obvious since actual salaries and benefits are applied

UCLA Non-Refundable Start-Up Fee
ITEM
Study Approval Process: High Study Complexity (includes Site Initiation Visit)
Study Approval Process: Moderate Study Complexity (includes Site Initiation Visit)
Study Approval Process: Basic (includes Site Initiation Visit)
Study Maintenance - INVBL (Efforts performed by Study Team)
Annual Committee Renewals
Amendment/Investigator Brochure with/without ICF changes with Ancillary resubmission
Amendment/Investigator Brochure with/without ICF changes.
Additional IRB Modification (Low Complexity)
Re-Consent per participant
Sub-study ICF (or any other additional consenting)
Med Watch / IND Safety Report/SAE Submission per report --- First 10 Reports are free. Invoicing starts with the 11th report.
Audit Preparation/Performance: per hour, per research staff (up to 8 hours)
Audit Preparation/Performance: per hour, per Research staff (8+ hours/OT)
Audit Preparation/Performance: per hour, per PI
Monitor Maintenance Visit: Study Team Remote or On-Site Monitoring per day (applicable if UCLA faculty and/or staff visit participation is required)
Monitor Close out Visit: Study Team Remote or On-Site Monitoring, per day (applicable if UCLA faculty and/or staff visit participation is required)
Study Closure
Pre-Screening Log, Cost Per Patient
Unscheduled Visits (Time and Effort Only)

Ancillary Recharges

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Ancillary Recharges / Department Costs

- *How* are Ancillary/Department Costs determined?
 - Stakeholders conformed of several departments are vital in determining costs for items and presented to Pricing Committee for review and approval. Procurement teams must adopt a detailed approach while estimating the cost per components.
- *What* is considered to determine these Costs?
 - During clinical trials, the cost of tests are higher to offset inflation. The study will be able to pay for services that increased in later years.
- Common Ancillary costs in Clinical Trials come from:
 - Clinical & Translation Research Center (CTRC)
 - Clinical and Translational Science Institute (CTSI)
 - Specialty departments- Pathology, Pharmacy, Radiology



Ancillary Recharges / Dept Costs

- Why are some costs significantly *more* than others?
 - Due to specific procedural requirements, it is possible that physicians perform specialized tests for particular disease indications along with regular physical examinations of patients. This may require more physician time that results in higher costs.
 - If an item/procedure quote at actual cost is requested due to it not being your contracted budget and quote is not what PI had in mind, always get these approvals from the UCLA Pricing Committee. These matters need to be discussed with all appropriate stakeholders of the committee prior to getting costs approved.

Hard vs Soft Costs

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CPT Codes

- What are **Current Procedural Terminology (CPT)** code examples?
 - CPT 81005 Urinalysis
 - CPT 99201-99215 Physical Exam / Office Visit
 - CPT 36415 Venipuncture/Blood Draw/Specimen Collection
- Why are **CPT codes** used?
 - Improves collection and revenue and to meet budget projections
 - Prevents mischarging of procedures to the subject's insurance or to the clinical trial
 - Authorizes procedures for each subject based on the study they are enrolled on
 - Provides template of procedures, which is generated for each patient enrolled
 - Confirms what should be billed to the account for pre-invoicing

Hard vs Soft costs

- What are **hard costs vs soft costs** in clinical trials?
 - **Hard costs** are Procedural items that are associated with a Current Procedural Terminology (CPT) and accrued during a clinical trial project
 - Ex. Bone Marrow Biopsy (CPT 77084)
 - **Soft costs** are more study team cost related not directly tied to CPT related costs.
 - Ex. Bone Marrow Handling (no CPT) and shipping fee (no CPT)
- Both costs are very common in development of **Industry (For-Profit)** budgets
 - These terms are meant to distinguish between different types of costs with regards to their relationship to the overall construction of budget
 - The proportion of hard cost to soft cost will vary from project to project

Non-Profit vs For-Profit (Industry) Rates

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Non-Profit vs For-Profit (Industry) Rates

- Non-Profit

- Rates are **actual rates** at cost listed on budget agreements
- All rates for funded clinical trials (regardless of Protocol authorship) are subject to Facilities and Administrative Costs (F&A)
- Patient care items related to the object code 3466 are excluded from the overhead

- For-Profit

- Rate are **negotiated costs**, reviewed and approved budget agreements.
- All rates for funded clinical trials (regardless of Protocol authorship) are subject to Facilities and Administrative Costs (F&A)

- Current **F&A Rates**

Sponsor Type	Agreement Type	Contract Office	Current F&A rate (as of 09/27/24)
Non-Profit	Clinical Trial	OCGA	57.5%
Non-Profit	Clinical Research	OCGA	57.5%
For-Profit (Industry)	Clinical Trial	CTC&SR	33%
For-Profit (Industry)	Clinical Research	TDG	57.5% on campus 26% off campus

Review & FAQ

CLINICAL TRIALS

Review

- The **costs** we've discussed are reflected on our budgets
 - A **for-profit** (industry) budget will have salary costs & patient care costs built in the per-subject budget. Both **will have UCLA overhead assessed to the direct costs**.
 - For a **non-profit** budget, salaries will be assessed the applicable UCLA overhead to the direct costs and patient care costs that fall under **object code 3466 are not assessed UCLA overhead**.
- Salaried Costs (time & effort for study personnel)
 - Common personnel include Principal Investigator, Study Coordinator, Data Manager, Research Assistant, Regulatory, etc.
- Patient Care Costs
 - **Patient care procedures and assessments** are driven from Schedule of Events (SOE) located in protocol and mostly have **CPT codes**, which are used to determine the amount of reimbursement that a practice will receive for that service

Cost - Review

- Invoiceable Administrative Costs (Pass Thru Costs)
 - **Administrative salary costs** are typically associated with time and effort for study personnel
 - Administrative start-up, amendments & annual renewals, protocol amendment preparation, AE/SAE management, safety reports, audits – time & effort of Study Team. Refer to **CT Industry Budget - Invoiceable Salary Related Costs**
- Invoiceable/Conditional Subject Costs (Pass Thru Costs)
 - Subject related items performed as needed and not for all subjects
 - i.e. shipping/courier fees including packaging/dry ice for samples, subject travel for visits, pregnancy test, screen failures (quantity/cap allowed and amount per screen fail)
- Invoiceable Ancillary/Dept and 3rd Party Costs (Pass Thru Costs)
 - Supporting UCLA departments and outside companies who provide services
 - IRB/Bruin IRB fees – Initial, recruitment/advertising Costs, pharmacy review and set-up Fees, document translation costs, publication fees, Translation of Informed Consent, device /equipment purchases, document/file storage

FAQ

- What do I do if item is *NOT* found on a contract budget?
 - If study team asks for a rate, these rates **MUST** be channeled through DOM CTP. Department rates are provided to study team prior to quoting sponsor cost. Kindly send your requests to DOMCTP@mednet.ucla.edu for DOM Department Rate
 - Our Department Rates include consideration of offsets, unforeseen costs, and inflation
 - Once Department rate is provided, the new item will be added to DOM Cost List and Charge Master



Links from Today's Class

- CT Budget & Cost Related Resources
 - [Clinical Research Billing - Research Charge Master](#)
 - [Facilities and Administrative Costs \(F&A\)](#)
 - DOM Cost List – request from [DOM CTP](#)
- DOM Clinical Trials Research Administrator Manual Chapters
 - [CT Acronyms & Key Terminology](#)
 - [Patient Care Budget Template](#)
- Contacts
 - DOMCTP@mednet.ucla.edu – General inquiries
 - CoverageAnalysis@mednet.ucla.edu – Billing calendar in OnCore
 - UCLAHSCRBP@mednet.ucla.edu – Research Billing and Coding

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!