

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>

# Introduction to Clinical Trials Budgeting, Billing & Financial Management

UCLA DEPARTMENT OF MEDICINE  
OFFICE OF RESEARCH ADMINISTRATION  
ZOOM TRAINING

# Summary

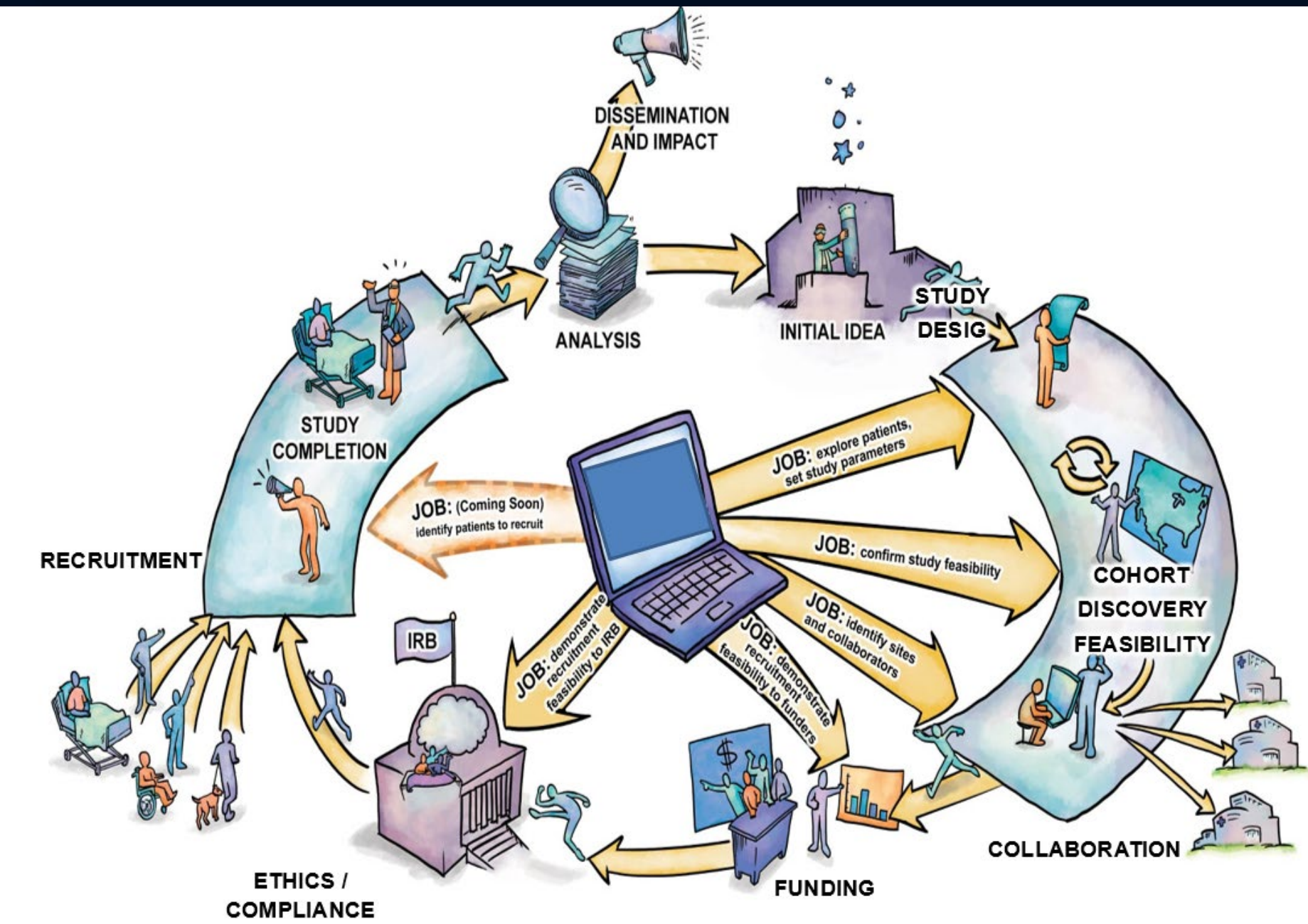
- Introduction to Clinical Trials (CT)
  - Description & flow
  - Contract Office contacts
  - Key terminology & acronyms
- Budgeting, Billing & Financial Management of a CT
  - Financial lifecycle
  - CT Start-Up process / Pre-Award
  - Financial Management - Charge Review
  - CT Close-Out process

# Introduction

## CLINICAL TRIALS

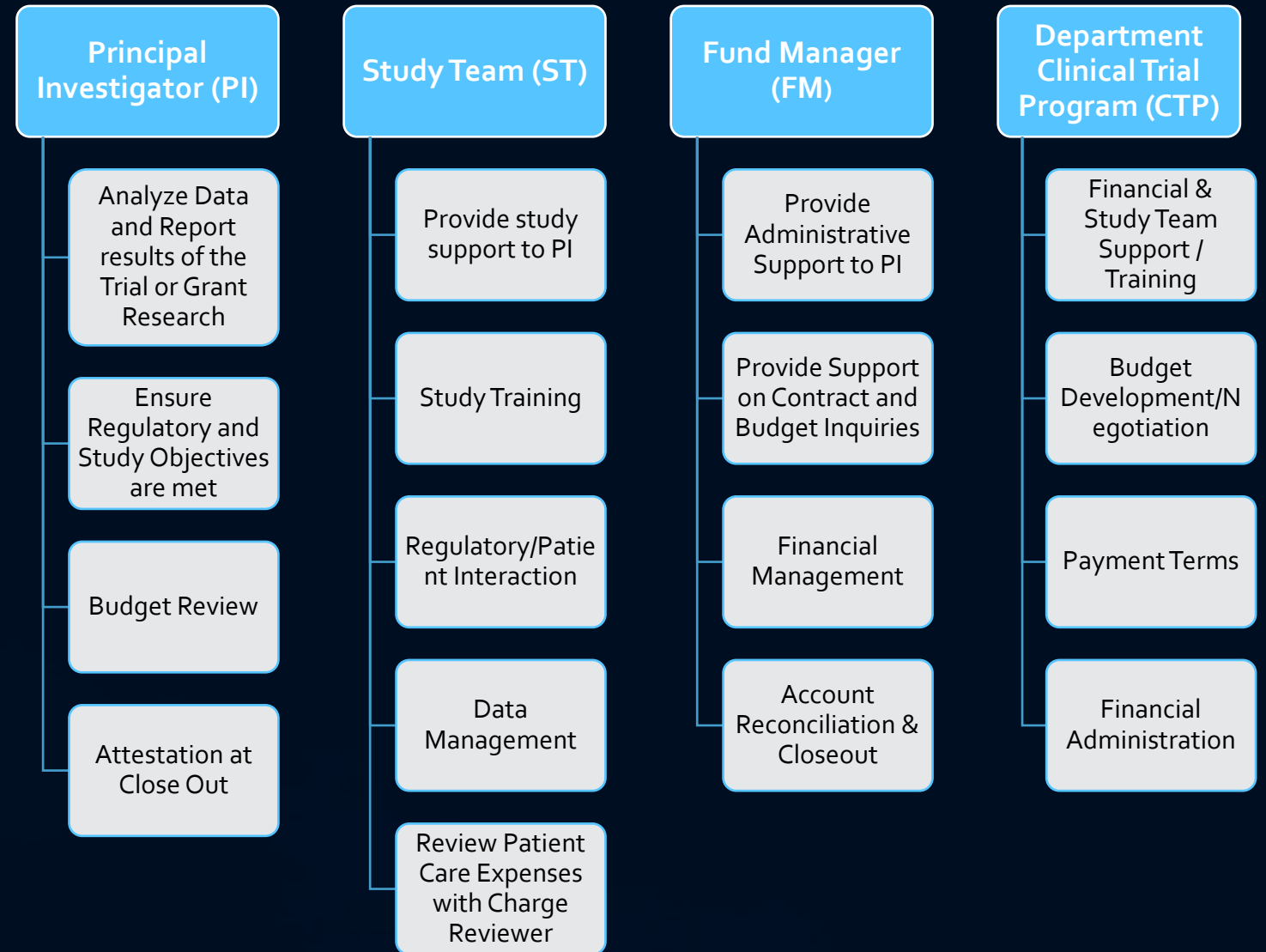
# Clinical Trial - Description

- Clinical trials are experiments designed to evaluate new interventions to prevent or treat disease in humans. The interventions evaluated can be drugs, devices (e.g., hearing aid), surgeries, behavioral interventions (e.g., smoking cessation program), community health programs (e.g. cancer screening programs) or health delivery systems (e.g., special care units for hospital admissions).
- Results from randomized clinical trials are usually considered the highest level of evidence for determining whether a treatment is effective because trials incorporate features to ensure that evaluation of the benefits and risks of treatments are objective and unbiased. The FDA requires that drugs or biologics (e.g., vaccines) are shown to be effective in clinical trials before they can be sold in the US.



# Roles

- Principal Investigator
- Study Team
- Fund Manager
- Clinical Trial Program



# UCLA Central Pre-Award Offices

- FOR-PROFIT/INDUSTRY SPONSOR → **CTC&SR** or **TDG**
  - Clinical Trials only – Clinical Trials Contracts & Strategic Relations (CTC&SR)
  - Research Contracts & Grants (excluding Clinical Trials) – Technology Development Group (TDG)
- NON-PROFIT SPONSOR → **OCGA**
  - Contracts – OCGA Officer
  - Grants & Cooperative Agreements – OCGA Analyst
  - Clinical Trials – OCGA Analyst or OCGA Officer
  - Grants.gov Grants/S2S ≤ \$500K – **DOM DRA** (*DOM only*)

Sponsors Types	Contracts	Grants Cooperative Agreements	Clinical Trials
Non-Profit	<b>OCGA / DOM DRA*</b>	<b>OCGA / DOM DRA*</b>	<b>OCGA</b>
For-Profit/Industry	<b>TDG</b>	<b>TDG</b>	<b>CTC&amp;SR</b>
* for grants.gov applications ≤ \$500,000 DC/year, except Ts (training) and F (fellowship) series			

# UCLA Central Pre-Award Offices & Contacts

- [Clinical Trial, Contracts and Strategic Relations \(CTC&SR\)](#)
  - CTC&SR Intake Team - [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)
  - Purpose: Negotiate agreements such as [confidentiality agreements \(CDA\)](#) related to clinical trials and [clinical trial agreements \(CTA\)](#) for industry supported drug, biological and medical device trials, and is the authorized institutional signatory for these agreements. [FOR PROFIT](#) pharmaceutical, biomedical and medical device manufactures as well as [contract research organizations \(CRO\)](#). In addition, [CTC&SR negotiates CDAs and CTAs with non-profits that flow through Industry funding](#): New, Amended and No Cost Time Extension on contracts. Also send Internal Documents. Email should include PATS# (if assigned), PI, sponsor & protocol name.



# UCLA Central Pre-Award Offices & Contacts

- [Technology Development Group \(TDG\)](#)
- DOM contacts
  - Non-HemOnc: Tara Davidoff ([Tara.Davidoff@tdg.ucla.edu](mailto:Tara.Davidoff@tdg.ucla.edu))
  - HemOnc: Karla Zepeda ([KZepeda@tdg.ucla.edu](mailto:KZepeda@tdg.ucla.edu))
- Other department [TDG Contacts/Assignments](#)
- Purpose: Industry supported basic and applied research, including **material transfer agreements (MTA)**: New, Amended and **No Cost Time Extension (NCTE)** on contracts. The UCLA **Technology Development Group (TDG)** handles various agreements involving research funded at UCLA by [FOR-PROFIT/INDUSTRY sponsors](#). If your research will involve interactions with and funding from industry sponsors, TDG Contract Officers will help with the process. Also send Internal Documents. Email should include PATS# (if assigned), PI, sponsor & protocol name.

# UCLA Central Pre-Award Offices & Contacts

- [Office of Contract & Grant Administration \(OCGA\)](#)
  - OCGA Intake reach out directly to your OCGA Analyst or Officer [DOM Division Contacts/Assignments](#)
  - Purpose: Submission for extramurally funded research proposals to government, non-profit and higher education organizations for the purpose of research, service, training, clinical trials, and other sponsored activities. The review and approval and signing and/or submitting of all proposals to government, [NON-PROFIT](#), and higher education organizations for extramural support on behalf of the University. This includes sponsored project activities, such as research, training, and public service.

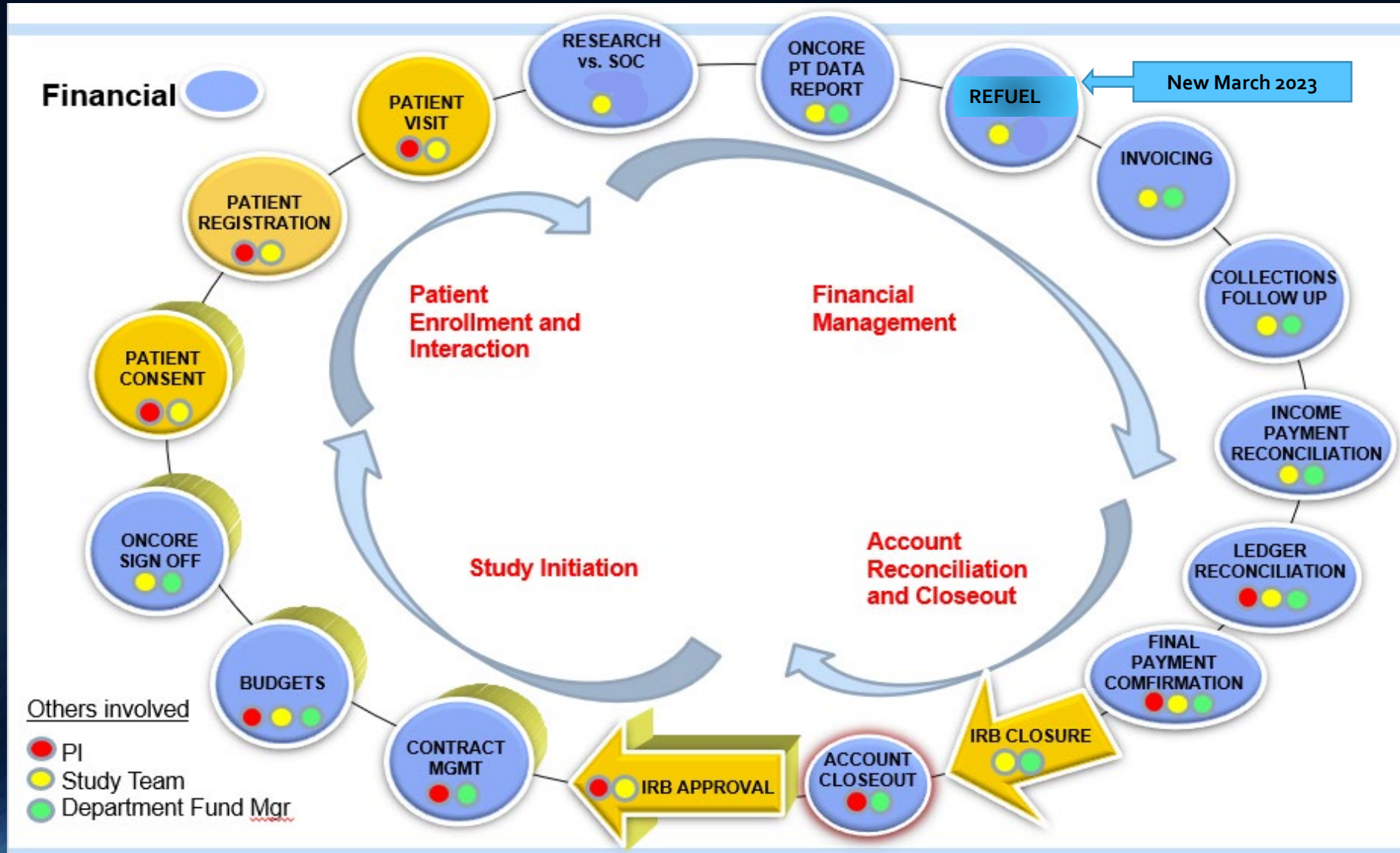
# CT Key Terminology & Acronyms

<b>PI</b>	Principle Investigator	<b>FCA</b>	Financial Coverage Analysis	<b>SOC / RC</b>	Standard of Care / Routine Care
<b>CRC</b>	Clinical Research Coordinator	<b>RQ</b>	Research Quality	<b>P / INV</b>	Pass through / Invoice Costs
<b>FM</b>	Fund Manager	<b>CRO</b>	Clinical Research Organization	<b>SAE</b>	Serious Adverse Events
<b>REG</b>	Regulatory	<b>CRC</b>	Clinical Research Coordinator	<b>Industry</b>	For Profit
<b>RTR</b>	Research Transaction Report (Billing)	<b>SIV</b>	Site Initiation Visit	<b>Government</b>	Non Profit
<b>CTC&amp;SR</b>	Clinical Trial, Contracts and Strategic Relations	<b>COV</b>	Close-Out Visit	<b>CT</b>	Clinical Trial
<b>TDG</b>	Technology Development Group	<b>IRB</b>	Institution Review Board	<b>CTA</b>	Clinical Trial Agreement
<b>OCGA</b>	Contract & Grant Officer Contacts	<b>CC</b>	Care Connect	<b>CTP</b>	Clinical Trial Program

# Budgeting, Billing & Financial Management

CLINICAL TRIALS

# Clinical Trial - Financial Life Cycle



# Start-Up / Pre-Award

CLINICAL TRIALS

# Required Documents for New/Amendment/NCTE

- Clinical Trial Intake
  - [CT Application Checklist – DOM](#)
- Obtain IRB, Consent & Protocol from Regulatory or Start –up Contact
- Draft Clinical Trial Agreement (CTA) with proposed budget numbers, obtain from Regulatory or Start –up Contact
- Obtain sponsor contact information from Regulatory or Start –up Contact
- If PI opts to outsource services
  - [DOM Clinical Trial Program \(CTP\) – Service Menu and Application Form](#)
  - Send your email request to (DOMCTP@mednet.ucla.edu)
  - [CTSI Clinical Research Coordination Services & Education \(CSE\) - List of Services](#)
  - Send your email request to (StudyActivation@mednet.ucla.edu)

# Organizations For-Profit vs Non-Profit

- **For-Profit Clinical Study** - funded extramurally by a for-profit organization. For Profit entities able to generate profit and meet long-term obligations.
- **Non-Profit Clinical Study** - funded extramurally by a governmental or non-profit organization, or internally funded through departmental/division funds, and/or other discretionary funds utilized by the PI (including but not limited to PI and staff time and effort used to conduct the Clinical Study).
- Despite their different approaches, for-profit and non-profit organizations share some financial reporting similarities, too. Both must carefully be tracked for all transactions; maintain supporting documentation; and produce accurate, timely financial statements.



# Certified Budget

- Research Quality Certified Budget – Sponsor / UCLA Worksheet
- UCLA Worksheet detailed Billing Grid/Matrix
  - Details all study events including patient procedures performed during each subject visit
  - It Drives where the service should be billed, who is financially responsible for the charge
  - Identifies each charge clearly as Third-Party (SOC or RC/RQ<sub>1</sub>) or Research (Sponsor Paid- S)
  - Billing Grid/Matrix should be used for each study participant as a roadmap to guide patient care charges
  - It serves as a vital tool when reconciling study charges

# Captured Costs

## Start-Up Costs

- PI and Team Effort - Investigator meeting, Site selection visit, Site Initiation, etc.
- Administrative Fees
- Study training
- Regulatory Document Preparation
- IRB preparation & review

## Event Based (Invoiceable) Fees – as applicable

- Annual IRB Preparation and Review
- IRB Amendment Preparation and Review
- Safety Report Preparation and Review
- Adverse Event Reports submissions
- Advertising Fees
- Monitoring/Audit Visit Fees
- Subject Visit Invoiceables (i.e. pregnancy tests)

# What are considered “Routine Costs” (RC)?

## Routine Costs – *Billable to insurer*

- Items or services that are typically provided absent a clinical trial (e.g., conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service- in particular, for the diagnosis or treatment of complications.

## Research-Only Costs – *Not Routine Care/Not Billable to insurer*

- The investigational item or service itself
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

# Evaluating the Sponsor Budget/Payment Terms

- Items for review:
  - Sponsor budget amount comparable to the UCLA internal budget per patient amount?
  - Who are Financial Coverage Analysis (FCA) what is their role? [Policy 915](#)
  - What is the initial payment/ start up?
  - What are the payment terms?
  - Is there a holdback for final payment?
  - Are hidden costs covered such as screen failure compensation, etc.?

# Negotiated Budget- CT Budget Template

Study Title: Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel Group, Multicenter, to Explore the Efficacy and Safety of DRUG in Patients XXXXX Disease																	Follow -up		IPD / IP	Unschedu	EXA visit	
Protocol Version: 2.0 December 16, 2019																	17		discontinua	led Visit		
Treatment Phase																	18		tion visit			
ARM	Screen	Run in	Cycle 1	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Cycle 12	End of Study	Total	Wk58	Wk64			
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16						
Each cycle is 28 Days	Day -42 to -35	Day -35	Wk 0	Wk4	Wk 8	Wk12	Wk16	Wk20	Wk24	Wk28	Wk32	Wk36	Wk40	Wk44	Wk48	Wk52						
<b>Staff Cost</b>																						
Principal Investigator	\$ 600	\$ 250	\$ 600	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 600	\$ 4,450	\$ 100	\$ 100	\$ 150	\$ 200	\$ 150
Study Coordinator	\$ 500	\$ 300	\$ 500	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 240	\$ 500	\$ 4,680	\$ 240	\$ 240	\$ 240	\$ 300	\$ 240
Data Manager	\$ 350	\$ 250	\$ 350	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 350	\$ 3,700	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200
<b>Procedures/ Assessments</b>																						
Informed Consent	\$ 300																\$ 300					
Office Visit / Physical Examination	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220	\$ 3,520	\$ 220	\$ 220	\$ 220	\$ 220	\$ 220
Medical history	X																\$ -					
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	\$ -	X	X	X		
Adverse Events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	\$ -	X	X	X		
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	\$ -	X	X	X	X	X
Weight	X		X													X	\$ -					
CAT	\$ 35		\$ 35			\$ 35			\$ 35			\$ 35			\$ 35	\$ 35	\$ 210			\$ 35		\$ 35
SGRQ		\$ 35	\$ 35			\$ 35			\$ 35			\$ 35			\$ 35	\$ 35	\$ 245			\$ 35		\$ 35
ePRO Compliance Check		\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 35	\$ 525			\$ 35		\$ 35
ePRO Home daily completion		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	\$ -			X		\$ -
EKG	\$ 158		\$ 158			\$ 158			\$ 158			\$ 158			\$ 158	\$ 158	\$ 948			\$ 158		\$ 158
<b>Radiology - Imaging</b>																						
Professional Radiology Reading	INVBL																\$ -					
MRI/CT	INVBL																\$ -					
CD Media Storage	\$ 45																\$ 45					
<b>Laboratory - Local</b>																						
Lab Specimen Collection	INVBL																\$ -					
Tuberculosis	INVBL																\$ -					
Pregnancy (Urine)	INVBL		INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	\$ -	INVBL	INVBL			
FSH	INVBL																\$ -					
<b>Laboratory - Central</b>																						
Lab Specimen Collection	75		\$ 75	\$ 75		\$ 75			\$ 75			\$ 75			\$ 75	\$ 75	\$ 600	\$ 75	\$ 75	\$ 75		\$ 75
Lab Specimen Processing	50		\$ 50	\$ 50		\$ 50			\$ 50			\$ 50			\$ 50	\$ 50	\$ 350	\$ 50	\$ 50	\$ 50		\$ 50
<b>Study Drug /Device</b>																						
Drug Dispensing Inj Fee			\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120	\$ 120		\$ 1,560					
Drug Administration /Accountability Inj Fee (DRUG/Placebo)			\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272	\$ 272		\$ 3,536					
<b>Miscellaneous</b>																						
CTRC Room	\$ 185		\$ 300	\$ 300	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 185	\$ 3,005	\$ 300	\$ 300	\$ 300		\$ 300
CTRC Staff	\$ 110		\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 110	\$ 1,650	\$ 110	\$ 110	\$ 110		\$ 110
Nutrition	\$ 50		\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 750	\$ 50	\$ 50	\$ 50		\$ 50
Parking	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	\$ -	INVBL	INVBL	INVBL	INVBL	INVBL
<b>Sub Total</b>	\$ 2,678	\$ 1,090	\$ 2,910	\$ 1,872	\$ 1,632	\$ 1,985	\$ 1,632	\$ 1,632	\$ 1,985	\$ 1,632	\$ 1,632	\$ 1,827	\$ 1,790	\$ 1,632	\$ 1,742	\$ 2,403	\$ 30,074	\$ 1,345	\$ 1,345	\$ 1,658	\$ 920	\$ 1,553
<b>Overhead 26%</b>	\$ 696	\$ 283	\$ 757	\$ 487	\$ 424	\$ 516	\$ 424	\$ 424	\$ 516	\$ 424	\$ 424	\$ 475	\$ 465	\$ 424	\$ 453	\$ 625	\$ 7,819	\$ 350	\$ 350	\$ 431	\$ 239	\$ 404
<b>Total w/ overhead</b>	\$ 3,374	\$ 1,373	\$ 3,667	\$ 2,359	\$ 2,056	\$ 2,501	\$ 2,056	\$ 2,056	\$ 2,501	\$ 2,056	\$ 2,056	\$ 2,302	\$ 2,255	\$ 2,056	\$ 2,195	\$ 3,028	\$ 37,893	\$ 1,695	\$ 1,695	\$ 2,089	\$ 1,159	\$ 1,957
<b>Anticipated enrollment 8</b>																	<b>Total of 8 patients</b>					
X: Cost included in budget																	Total Direct	\$ 240,592				
* / INVBL: Invoice to sponsor																	Total Indire	\$ 62,554				
Q1 / RC1: ROUTINE CARE																	Total Costs	\$ 303,146				
<b>Invoiceables Schedule B</b>																						

# Negotiated Budget- Fixed Costs & Procedure Costs

## Event Based / Invoiceable Fees

- Most typical budgets consist of per subject/per visit amount and various invoiceable items, often a mix of invoiceable clinical procedures and administrative and institutional costs

<b>NON-REFUNDABLE FIXED COSTS FOR UCLA</b>				<b>Direct Costs</b>	<b>Indirect Costs</b>	<b>Total</b>	<b>Pagable</b>
Study Approval Process: Application Preparation & Submission to: IRB, ISPRC, MRSC, CA and Pharmacy	\$	3,000	\$	2,340	\$	11,340	Upon full execution of agreement
Site Initiation Visit: Time & Effort	\$	1,500	\$	390	\$	1,890	Upon full execution of agreement
Mandatory UCLA IRB Fees	\$	2,500			\$	2,500	Upon full execution of agreement
Pharmacy Set-up Fees	\$	3,000	\$	780	\$	3,780	Upon full execution of agreement
Pathology and Laboratory Medicine Set-Up Fee	\$	4,000	\$	1,040	\$	5,040	Upon full execution of agreement
Radiology Set-Up Fee	\$	750	\$	195	\$	945	Upon full execution of agreement
CTRC Set-up Fee	\$	2,391	\$	622	\$	3,013	Upon full execution of agreement
<b>Total Non-Refundable Fixed Costs</b>					<b>\$</b>	<b>28,508</b>	

<b>Items</b>	<b>Direct Costs</b>	<b>Indirect Costs</b>	<b>Total</b>	<b>Pagable</b>			
Committee Annual Committee Renewals:	\$	2,850	\$	741	\$	3,591	Annually upon invoice
Pharmacy Renewal Fees	\$	1,500	\$	390	\$	1,890	Annually upon invoice
Protocol Amend/IB Amendment with ICF Changes	\$	500	\$	130	\$	630	Upon submission of invoice
Informed Consent Form with Changes	\$	630	\$	164	\$	794	Upon submission of invoice
Reconsent per participant	\$	99	\$	26	\$	125	Upon submission of invoice
Pharmacy Monitoring Visit Fee: \$150/hr for first hour	\$	150	\$	39	\$	189	Upon submission of invoice
Pharmacy Monitoring Visit Fee: \$125/hr, beyond 1st hour	\$	125	\$	33	\$	158	Upon submission of invoice
Pharmacy Protocol Updates per update	\$	300	\$	78	\$	378	Upon submission of invoice
Pharmacy Sponsor Requests for Additional Pharmacy Data after Closeout Visit: Annual Maintenance Fee + Monitoring Fee	\$	1,650	\$	429	\$	2,079	Upon submission of invoice
ICF TRANSLATION**			Actual Cost Plus 26% Indirect Costs				Upon submission of invoice
Copying and Long Term Storage (per pt)	\$	350	\$	91	\$	441	Upon submission of invoice
Pharmacy Close-Out Fee	\$	500	\$	130	\$	630	Upon submission of invoice
Study Closure	\$	500	\$	130	\$	630	Upon submission of invoice
Med Watch/IND/SAE Safety Report Submission per report	\$	35	\$	9	\$	44	Upon submission of invoice

<b>Procedures</b>	<b>Direct Costs</b>	<b>Indirect Costs</b>	<b>Total</b>	<b>Pagable</b>			
Professional Radiology Reading Fee	\$	330	\$	101	\$	431	Upon submission of invoice
Chest X-Ray	\$	251	\$	65	\$	316	Upon submission of invoice
CT Abdomen	\$	669	\$	174	\$	843	Upon submission of invoice
CT Chest	\$	667	\$	173	\$	840	Upon submission of invoice
CT Pelvis	\$	651	\$	169	\$	820	Upon submission of invoice
MRI Abdomen	\$	1,092	\$	284	\$	1,376	Upon submission of invoice
MRI Pelvis	\$	1,174	\$	305	\$	1,479	Upon submission of invoice
CD Media Storage Fee (per disk)	\$	45	\$	12	\$	57	Upon submission of invoice

<b>Misc</b>	<b>Direct Costs</b>	<b>Indirect Costs</b>	<b>Total</b>	<b>Pagable</b>			
Audit Preparation Fee	\$	1,000	\$	260	\$	1,260	Upon submission of invoice
Serious Adverse Event (study team time and effort: Initial/Follow-Up/Resolution) Per Event	\$	500	\$	130	\$	630	Upon submission of invoice
Study Re-Open Process: Application preparation and submission to IRB, IMV	\$	1,500	\$	390	\$	1,890	Upon submission of invoice
Staff Time and Effort (Regulatory Coordinator & Study Coordinator) for Study Re-Open Process	\$	450	\$	117	\$	567	Upon submission of invoice
Storage Record Retrieval Fee for Study Re-Open Process	\$	300	\$	78	\$	378	Upon submission of invoice
Survival Follow-up, per patient, per phone contact.	\$	153	\$	41	\$	200	Upon submission of invoice
Ancillary Services CTRC Outpatient Room/Procedure Room (each add'l hour)	\$	150	\$	39	\$	189	Upon submission of invoice
Ancillary Services CTRC Staff (each add'l hour)	\$	150	\$	39	\$	189	Upon submission of invoice
Ancillary Services CTRC Equipment Storage (Small: Sponsor EKG)	\$	500	\$	130	\$	630	Upon submission of invoice
Patient Nutrition	\$	50	\$	13	\$	63	Upon submission of invoice
Parking	\$	20	\$	5	\$	25	Upon submission of invoice
Transportation (Uber/LiFTaxi, etc)			Actual Cost Plus 26% Indirect Costs				Upon submission of invoice
Pt Travel (Mileage, hotel, airfare, etc)			Actual Cost Plus 26% Indirect Costs				Upon submission of invoice
Screen Failures****	\$	2,678	\$	696	\$	3,374	Upon submission of invoice

# Financial Management - Charge Review

CLINICAL TRIALS

# Financial Management & Administrative Responsibilities

<b>Principal Investigator (PI)</b>	<ul style="list-style-type: none"><li>• Monthly review of expenditures</li><li>• Approve expenses</li><li>• Allocation of effort</li><li>• Provide updates on upcoming occurrences (study on hold, closure, etc.)</li></ul>
<b>Study Team (ST)</b>	<ul style="list-style-type: none"><li>• Enrollment Log(s)</li><li>• Log participant in OnCore as well as Sponsor EDC systems;</li><li>• Reconcile patient care billing to patient enrollment in collaboration with Fund Manager</li><li>• Maintain Study Binder</li><li>• Data collection</li></ul>
<b>Department Fund Mgr (FM)</b>	<ul style="list-style-type: none"><li>• Process salary and expense transactions</li><li>• Monthly review of salary &amp; expenditures</li><li>• Make adjustments/corrections based on salary reports</li><li>• Update projections</li><li>• Track patient data and Invoice sponsor</li><li>• Monthly reconciliation of patient care charges with Study Team &amp; Ancillary Depts</li><li>• Provide administrative/financial support to PI</li></ul>
<b>Clinical Trial Program (CTP)</b>	<ul style="list-style-type: none"><li>• Financial Training / Support</li><li>• Budget Development / Negotiation &amp; Budget Payment Terms and Conditions</li><li>• Account Reconciliation &amp; Closeout support</li><li>• Administrative Start-up Support</li></ul>



# Patient Related Charges

- The [REFUEL- March 2023](#) are charges in Care Connect that patients are linked to research account for Charge Review. These charges are reviewed by DOM central Charge Reviewing Unit. The data entered by study team in OnCore systems will assist Charge Reviewers in identifying charge adjudication. A few things to consider...
  - Are all patients charges to the study truly part of the study?
  - Are there any patients that you do not see on your list that you know participated?
  - Are some of these charges not related to the study?
  - Are some of the charges listed incorrectly?
- NOTE: Charges should be hitting account at the actual cost/non profit rate. Budget contracted is only the amount we should be invoicing for.

# Close-Out

## CLINICAL TRIALS

# Close-Out Responsibilities

<b>Principal Investigator (PI)</b>	<ul style="list-style-type: none"><li>• Final reconciliation of all expenses</li><li>• Attestation that all expenses are allocable and appropriate for the trial</li><li>• Resolution of any deficit</li></ul>
<b>Study Team (ST)</b>	<ul style="list-style-type: none"><li>• Ensure all patient data has been submitted to sponsor</li><li>• Work with Fund Mgr to ensure sponsor has been billed for everything related to the clinical trial</li><li>• Work with Fund Mgr to ensure communication with respect to patient status and patient data.</li></ul>
<b>Department Fund Mgr (FM)</b>	<ul style="list-style-type: none"><li>• Reconcile expenses</li><li>• Transfer / correction of any inappropriate expenses</li><li>• Ensure all anticipated costs have hit account</li><li>• Prepare residual balance transfer form</li><li>• Resolution of any deficit</li></ul>

# Closing a Clinical Trial Account

The processes should include:

- Completion of a final account reconciliation prior to closure.
- [DOM CT Checklist](#)
  - Includes checks for receipt of proper documentation to authorize account closure.
    - ✓ Written correspondence from sponsor indicating closure for site.
    - ✓ Written confirmation from sponsor of final payment.
    - ✓ Notice of IRB Completion/Termination (can not close until final payment made)
- Verification that the account close-out(s) have occurred by EFM (Y/N'd).

NOTE: Keep in mind for balances [greater than 25% of the total cost](#), the PI is required to provide additional justification for the large unexpended balance.

## Policy 913: Disposition of Unexpended Balances in Fixed Rate and Fixed Price Contracts and Nonrefundable Grants

- When is Policy 913 applicable?
  - This policy applies if there is an unexpended balance remaining after close-out of an expired or terminated fixed price or fixed rate contract or nonrefundable grant. Funds will be transferred into the PI's account/cc linked to Fund 69970.
- Who processes Policy 913 Transfers to fund 69970?
  - Campus departments are responsible for confirming Policy 913 fund transfers by EFM as the last step of the close out process. Upon receipt of the request and Closeout Packet, EFM will transfer the unexpended balance amount to the department's designated account/cost center and fund 69970.
- EFM Contact by Department/Division

# Review of Key Points

- PI is responsible for all aspects of a clinical trial throughout the lifecycle, with assistance from Study Team and Department Fund Mgr
- Internal budget development is necessary to determine if sponsor budget will support the trial and how services will be expensed.
- CTP will assist with budget negotiation, payment terms and budget development as needed
- PI, Study Team and Fund Mgr are responsible for the post-award monitoring of expenses posted to the clinical trial activity number (Financial Management)
- PI works with Fund Mgr for attesting that all charges are appropriate prior to account closeout

# Do You Have a Clinical Trial Inquiry?

Submit your inquiries to DOM Clinical Trial Program  
([DOMCTP@mednet.ucla.edu](mailto:DOMCTP@mednet.ucla.edu))

Services offered:

- Regulatory and Fund Manager Services
- Training including group and 1-on-1 sessions
- Clinical trial start-up, maintenance and closure
- OnCore guidance and navigation
- CSE SOW department signature
- Any general Clinical Trial related questions and inquiries

# Links from Today's Class

- Clinical Trials Supporting Offices & Contacts
  - [DOMCTP \(DOMCTP@mednet.ucla.edu\)](mailto:DOMCTP@mednet.ucla.edu)
  - [CTSI CSE \(StudyActivation@mednet.ucla.edu\)](mailto:StudyActivation@mednet.ucla.edu)
  - [CTC&SR \(clinicaltrials@mednet.ucla.edu\)](mailto:clinicaltrials@mednet.ucla.edu)
  - [OCGA \(proposals@research.ucla.edu\)](mailto:proposals@research.ucla.edu)
  - [TDG \(Dept Assignments\)](#)
  - [EFM \(Dept Assignments\)](#)
- DOM Clinical Trials Fund Manager Manual Chapters
  - [CT Acronyms & Key Terminology](#)
  - [CT Application Checklist](#)
  - [CT Budget Template](#)



# 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!