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

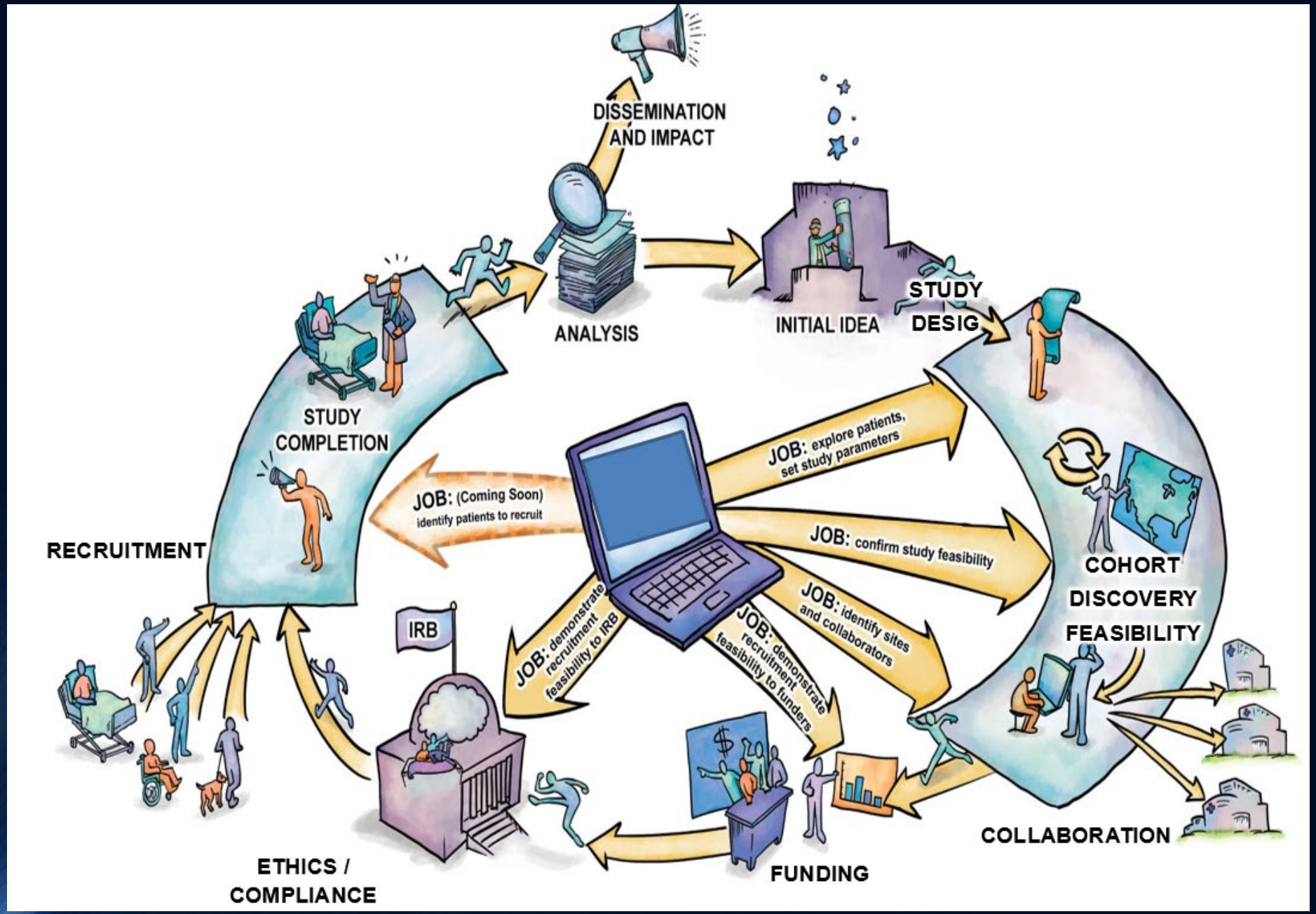
- What are Clinical Trials?
  - Clinical trials are experiments designed to evaluate new interventions to prevent or treat disease in humans. The interventions evaluated can be drugs, devices (e.g., hearing aid), surgeries, behavioral interventions (e.g., smoking cessation program), community health 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 incorporates 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.
- Why are they important?
  - Clinical trials are crucial for determining if new treatments are safe and effective.

UCLA Clinical Trial - Definition

- How do I determine if the research is a clinical trial?
  - A Clinical trial is defined with the NIH definition, as a research study where participants are assigned to interventions to assess the effects on health-related outcomes. This includes drug, biological, and medical device trials, both for-profit and non-profit.
    - Does the study involve human participants?
    - Are the participants prospectively assigned to an intervention?
    - Is the study designed to evaluate the effect of the intervention on the participants?
    - Is the effect being evaluated a health-related biomedical or behavioral outcome?
  - If the answer to all four questions is "yes," then the clinical study would be considered a clinical trial according to the NIH definition.

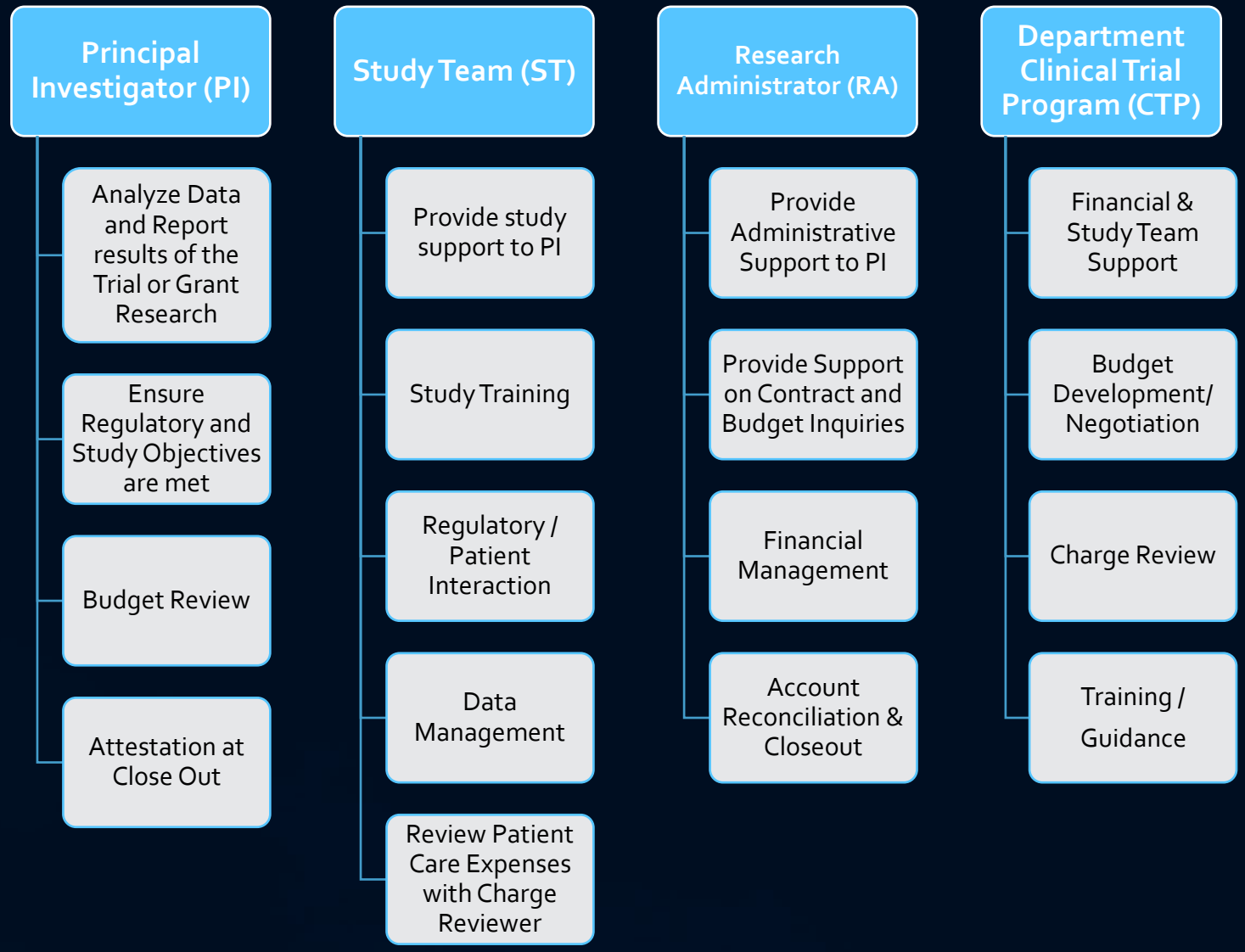
UCLA Protocol definition Policy 916:

- At UCLA, a protocol is a detailed plan for a research study, particularly a clinical trial, outlining its objectives, design, methodology, and procedures. It serves as a roadmap for conducting the research, ensuring it's conducted safely, ethically, and according to established guidelines
  - Clinical Trials Focus: Protocols are crucial for clinical trials, ensuring they are conducted safely and ethically, and that data is collected accurately and reliably.
  - Ethical Considerations: Protocols also address ethical considerations, such as the protection of human subjects.
  - Compliance: They ensure adherence to relevant guidelines, like the International Conference on Harmonization (ICH) E6 Good Clinical Practice guidelines.
  - UCLA Specifics: At UCLA, the Office of the Human Research Protection Program (OHRPP) is involved in reviewing and approving protocols to ensure they meet the university's standards for ethical research involving human subjects.


DISSEMINATION AND IMPACT
ANALYSIS
INITIAL IDEA
STUDY DESIG
STUDY COMPLETION
RECRUITMENT
JOB: (Coming Soon) identify patients to recruit
JOB: explore patients, set study parameters
JOB: confirm study feasibility
JOB: identify sites and collaborators
JOB: demonstrate recruitment feasibility to funders
JOB: demonstrate recruitment feasibility to IRB
IRB
COHORT DISCOVERY FEASIBILITY
COLLABORATION
FUNDING
ETHICS / COMPLIANCE

Roles

- Principal Investigator
- Study Team
- Research Administrator
- Clinical Trial Program



UCLA Central Pre-Award Offices

- What are the 3 Contract Offices?

1. 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)*

2. FOR-PROFIT/INDUSTRY SPONSOR → TDG
   - Research Contracts & Grants (excluding Clinical Trials) – Technology Development Group (TDG)

3. FOR-PROFIT/INDUSTRY SPONSOR → CTC&SR
   - Clinical Trials only – Clinical Trials Contracts & Strategic Relations (CTC&SR)

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

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.

UCLA Central Pre-Award Offices & Contacts

- Technology Development Group (TDG)
  - DOM TDG contacts
  - 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

- Clinical Trial, Contracts and Strategic Relations (CTC&SR)
  - CTC&SR Intake Team - 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.

CT Key Terminology & Acronyms

PI	Principle Investigator	**FCA**	Financial Coverage Analysis	**SOC / RC**	Standard of Care / Routine Care
CRC	Clinical Research Coordinator	**RQ**	Research Quality	**P / INV**	Pass through / Invoice Costs
RA	Research Administrator	**CRO**	Clinical Research Organization	**SAE**	Serious Adverse Events
REG	Regulatory	**CRC**	Clinical Research Coordinator	**Industry**	For Profit
RTR	Research Transaction Report (Billing)	**SIV**	Site Initiation Visit	**Government**	Non Profit
CTC&SR	Clinical Trial, Contracts and Strategic Relations	**COV**	Close-Out Visit	**CT**	Clinical Trial
TDG	Technology Development Group	**IRB**	Institution Review Board	**CTA**	Clinical Trial Agreement
OCGA	Contract & Grant Officer Contacts	**CC**	Care Connect	**CTP**	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
- IRB, Consent & Protocol – can be obtained from Regulatory/start-up contact. (protocol available in OnCore)
- Draft Clinical Trial Agreement (CTA) with proposed budget amount, draft sponsor budget available in OnCore uploaded by Regulatory/start-up contact.
- Obtain Notice to Research Administrator form from your Regulatory/start-up contact to complete all necessary internal documents routed to contracts.
- If the PI doesn't have staff to conduct clinical research, here are options:
  - 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

- **What is a Certified Budget?**
  - Clinical Research Finance (CRF) Certified Budget – Sponsor / UCLA Worksheet
    - Policy 915
- **Why is Certification important?**
  - Worksheets that detail Billing Grid/Matrix serves as a vital tool when adjudicating and reconciling study charges. It provides the following:
    - 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/RQ1) or Research (Sponsor Paid- S)
  - Grid/Matrix should be used for each study participant as a roadmap to guide patient care charges

Captured Costs

Start-Up Costs

- Regulatory Document Preparation
- PI and Team Effort
  - Investigator meeting
  - Site selection visit
  - Site Initiation, etc.
- Study training
- Ancillary (Professional) Start up Fees

Event Based (Invoiceable) Fees – as applicable

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

What are "Routine Costs" (RC) items?

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

- What is involved in evaluating clinical trial budget:
  - Review the entire protocol: Look beyond just the bottom line, examining the overall scope and structure of the proposal.
  - Assess the budget's feasibility and thoroughness: Ensure the budget is reasonable and necessary for the project or event. Errors or omissions can disqualify a project for funding.
  - Determine if it matches your internal budget: Compare the sponsor's proposed budget amount (e.g., per patient in a clinical trial context) to your own internal budget for the project or event.
  - Understand the types of payment schedules: Sponsors may offer different payment structures, such as per-subject payments, invoiceable items, or site fees.

Negotiated Budget- CT Budget Template

Principal Investigator:		**Sponsor:**		Sponsor Contact		Institution Finance Contact:		Legend		Version	
Study Coordinator:		**Protocol:**						X = Cost bundled with other		Date	
Regulatory:		**Protocol Version:**						RC1 = bill to insurance		Approval	
		IRB:						INVBL = Bill to study			
Study Title: A Phase 3, Randomized, double Blind....											
	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19
	Screen	Day 1	Day 5	Day 8	Wk 2	Wk 4	Wk 8	Wk 16	Wk 24	Wk 32	Wk 40	Wk 48	Wk 56	Wk 64	Wk 72	EOT	*Follow #1*	*Follow #2*	*Follow #3*
*Principal Investigator Oversight Fee	$ 1,500	$ 1,500	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,500	$ 500	$ 500	$ 500
*Study Coordinator Fee	$ 1,500	$ 1,500	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,500	$ 500	$ 500	$ 500
*Data Manager Time	$ 1,200	$ 1,200	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,200	$ 400	$ 400	$ 400
Informed consent	$ 500																		
Physical Examination / Office Visit / Telehealth	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650	$ 650			
Inclusion / Exclusion criteria	X																		
Demography	X																		
Medical history/current medical conditions	X																		
Body Height	X																		
Body Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Assessment of fertility	X																		
Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
IRT Registration/Randomization		X																	
Questionnaire			$ 500	$ 500		$ 500	$ 500		$ 500	$ 500		$ 500	$ 500						
Leukapheresis				INVBL															
Forced Vital Capacity % (FVC%)		$ 1,200																	
Diffusing Capacity (DLCO/spirometry)																$ 1,600			
Single 12-lead ECG†					$ 450														
High Resolution CT of Chest		INVBL														INVBL			
Echocardiogram†		INVBL						RC1											
MUGA Scan or Cardiac ECHO		$ 2,500																	
Laboratory Specimen Collection/Draw - **Local**	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Clinical Chemistry	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Hematology	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Coagulation Panel	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Pregnancy test (serum)	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Pregnancy Test	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Influenza/SARS-COV2 testing	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL
Laboratory Specimen Collection/Draw - **Central**	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200
Laboratory Specimen Processing & Handling (Draw) - **Central** "Extensive"	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200
DNA collection (optional)		INVBL																	
Pharmacist-required IWRS Entry Fee		$ 150																	
Pharmacy IV Dose Dispensing (Drug Name)		$ 800.00	$ 800.00	$ 800.00	$ 800.00														
Drug Accountability/ Administration - IV Chemo/Biologic First Hour (Drug Name)		$ 850.00	$ 850.00	$ 850.00	$ 850.00														
Premedication- (Drug Name)		$ 400.00	$ 400.00	$ 400.00	$ 400														
Parking	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL	INVBL			
Subtotal (OnCore Procedure Items)	$7,750	$13,150	$9,000	$9,000	$8,950	$6,950	$6,950	$6,450	$6,950	$6,950	$6,450	$6,950	$6,950	$6,450	$6,450	$8,850	$3,800	$3,800	$3,800
Indirect Cost 33%)	$2,558	$4,340	$2,970	$2,970	$2,954	$2,294	$2,294	$2,129	$2,294	$2,294	$2,129	$2,294	$2,294	$2,129	$2,129	$2,921	$1,254	$1,254	$1,254
Total Cost	$10,308	$17,490	$11,970	$11,970	$11,904	$9,244	$9,244	$8,579	$9,244	$9,244	$8,579	$9,244	$9,244	$8,579	$8,579	$11,771	$5,054	$5,054	$5,054

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
  - *Note: Illustration not actual rates*

Non-Refundable Fixed Costs	UCLA Rate (Direct Cost)	Indirect Cost	Total Cost
Study Approval Process	*$45,000*	*$14,850*	*$59,850*
Site Initiation Visit: Time & Effort	*$5,000*	*$1,650*	*$6,650*
CTSI Research Services- Financial Start Up	*$5,500*	*$1,815*	*$7,315*
CTP Service Budget Negotiation Fee	*$5,500*	*$1,815*	*$7,315*
IRB Reliance Review Fee	*$5,500*	*NA*	*$5,500*
Pathology and Laboratory Medicine Set- Up Fee	*$5,500*	*$1,815*	*$7,315*
Radiology Set-up Fee	*$5,500*	*$1,815*	*$7,315*
Investigational Pharmacy Set-up	*$5,500*	*$1,815*	*$7,315*
CTRC Start up	*$5,500*	*$1,815*	*$7,315*
Remote Monitor EHR Setup Fee (includes study setup and provisioning up to one monitor for both HealthLink and eBinders)	*$5,500*	*$1,815*	*$7,315*
Total:	*$94,000*	*$29,205*	*$123,205*

Study Maintenance - INVBL (Efforts performed by Study Team)	UCLA Rate (Direct Cost)	Indirect Cost	Total Cost
Annual Committee Renewals	*$80,000*	*$26,400*	*$106,400*
Amendment/Investigator Brochure with/without ICF changes with Ancillary resubmission	*$6,000*	*$1,980*	*$7,980*
Amendment/Investigator Brochure with/without ICF changes.	*$5,000*	*$1,650*	*$6,650*
Additional IRB Modification Only	*$4,000*	*$1,320*	*$5,320*
CTP Service Budget Negotiation Amendment Fee	*$4,500*	*$1,485*	*$5,985*
Re-Consent per participant	*$350*	*$116*	*$466*
Sub-study ICF (or any other additional consenting)	*$900*	*$297*	*$1,197*
Med Watch / IND Safety Report/SAE Submission per report ---First 10 Reports are free. Invoicing starts with the 11th report.	*$6,000*	*$1,980*	*$7,980*
Monitor Maintenance Visit: Study Team Remote or On-Site Monitoring per day (applicable if UCLA faculty and/or staff visit participation is required)	*$6,000*	*$1,980*	*$7,980*
Monitor Close out Visit: Study Team Remote or On-Site Monitoring, per day (applicable if UCLA faculty and/or staff visit participation is required)	*$6,000*	*$1,980*	*$7,980*
Study Closure	*$6,000*	*$1,980*	*$7,980*
Phone Call visit each	*$800*	*$264*	*$1,064*
Follow-up per contact, per call (includes survival)	*$800*	*$264*	*$1,064*

Invoiceable Items	UCLA Rate (Direct Cost)	Indirect Cost	Total Cost
Advertisement	*$20,000*	*$6,600*	*$26,600*
ICF TranslationA	*$15,000*	*$4,950*	*$19,950*
Pharmacy Renewal Fee (annual)	*$5,000*	*$1,650*	*$6,650*
Pharmacy Monitor/Sponsor Visit Fee (Each Hour)	*$3,500*	*$1,155*	*$4,655*
Pharmacy Protocol Updates (per update)	*$3,500*	*$1,155*	*$4,655*

Financial Management - Charge Review

CLINICAL TRIALS

Financial Management & Administrative Responsibilities

- Managing the financial aspects of research awards.
- Monitoring expenditures and preparing financial reports.
- Reconciling accounts and ensuring compliance with award terms.
- Managing indirect cost recovery and other fund sources.
- Preparing and presenting research metrics reports.
- Serving as a liaison between PIs and various stakeholders.
- Ensuring adherence to institutional policies and procedures, including those related to human subjects research (if applicable).

Charge Review

- Effective financial management relies on accurate patient care charges to ensure correct reimbursement for services. Administrative staff manage billing and coding, ensure compliance, and handle claims. The review of patient care charges is a critical administrative function that directly impacts the organization's financial health.
- **UCLA Clinical Research Charge Review – Standard Operating Procedures**
  - A two-Tier Process:
    1) Tier 1 – Department of Medicine Charge Reviewer and Study Team are responsible for reviewing and approving charges that are reviewed in the Care Connect dashboard queue. Once charges are directed to (1) Study Related— Bill to Study, (2) Study Related – Bill to Patient's Insurance, and (3) Non-Study – Bill to Patient's Insurance, it will be submitted as reviewed then go to Tier 2.
    1) Tier 2 – CRBP unit will also review as a double-check on charges already approved by Tier 1 and address hiccups as necessary.
  - Processing Time: Charges are reviewed daily by Department of Medicine Charge Reviewers. All charges on Dashboard are reviewed timely. Both DOM and CRBP work together to assure timely approvals
  - Charges should be hitting account at the actual rates in accordance to the UCLA Charge Master. Contracted items are the amounts we should be invoicing for.

Close-Out

CLINICAL TRIALS

Close-Out Responsibilities

Principal Investigator (PI)	• Final reconciliation of all expenses • Attestation that all expenses are allocable and appropriate for the trial • Resolution of any deficit
Study Team (ST)	• Ensure all patient data has been submitted to sponsor • Work with Fund Mgr to ensure sponsor has been billed for everything related to the clinical trial • Work with Fund Mgr to ensure communication with respect to patient status and patient data.
Department Fund Mgr (FM)	• Reconcile expenses • Transfer / correction of any inappropriate expenses • Ensure all anticipated costs have hit account • Prepare residual balance transfer form • Resolution of any deficit

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 Research Administrator
- 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 Research Administrator are responsible for the post-award monitoring of expenses posted to the clinical trial activity number (Financial Management)
- PI works with Research Administrator for attesting that all charges are appropriate prior to account closeout

Do You Have a Clinical Trial Inquiry?

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

Services offered:

- Non Profit - Patient Care budget development
- For Profit –Budget Negotiation
- Research Staff
- Training/Guidance

Links from Today's Class

- Clinical Trials Supporting Offices & Contacts
  - DOM CTP (DOMCTP@mednet.ucla.edu)
  - CTSI CSE (StudyActivation@mednet.ucla.edu)
  - CTC&SR (clinicaltrials@mednet.ucla.edu)
  - OCGA (proposals@research.ucla.edu)
  - TDG (Dept Assignments)
  - EFM (Dept Assignments)
- DOM Clinical Trials Research Administrator 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!