This session will *not* be recorded, but this PowerPoint can found https://medschool.ucla.edu/research/researcher-resources/administrative-support/department-medicine-office-research-administration/fund-management-training

# Introduction to Clinical Trials

## Budgeting, Billing & Financial Management

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

# Summary

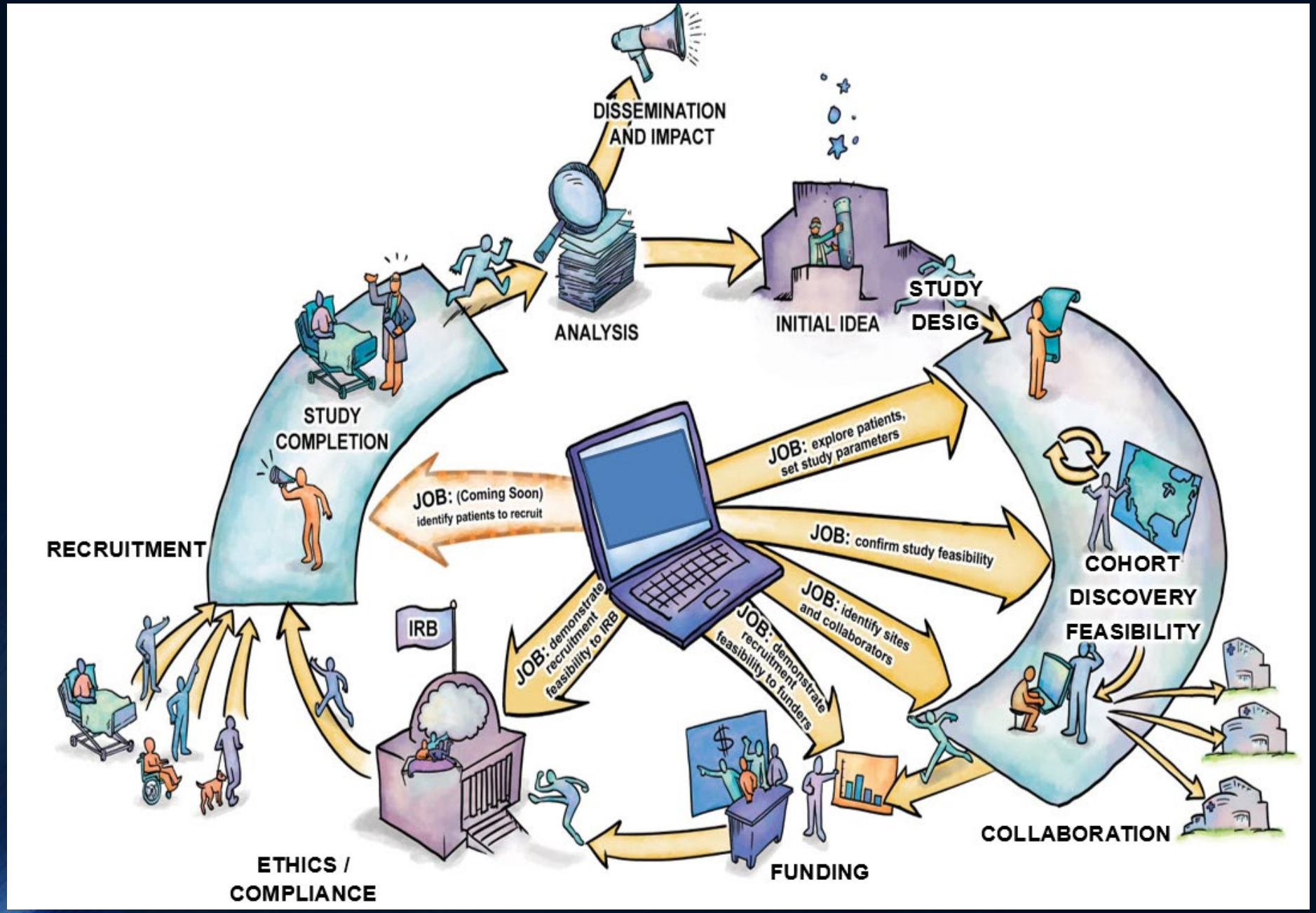
- Introduction to Clinical Trials (CT)
  - Description & flow
  - Contract Office contacts
  - Key terminology & acronyms
- Budgeting, Billing & Financial Management of a CT
  - Financial lifecycle
  - CT Start-Up process / Pre-Award
  - Financial management (charge capture) and account reconciliation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

# Introduction

## CLINICAL TRIALS

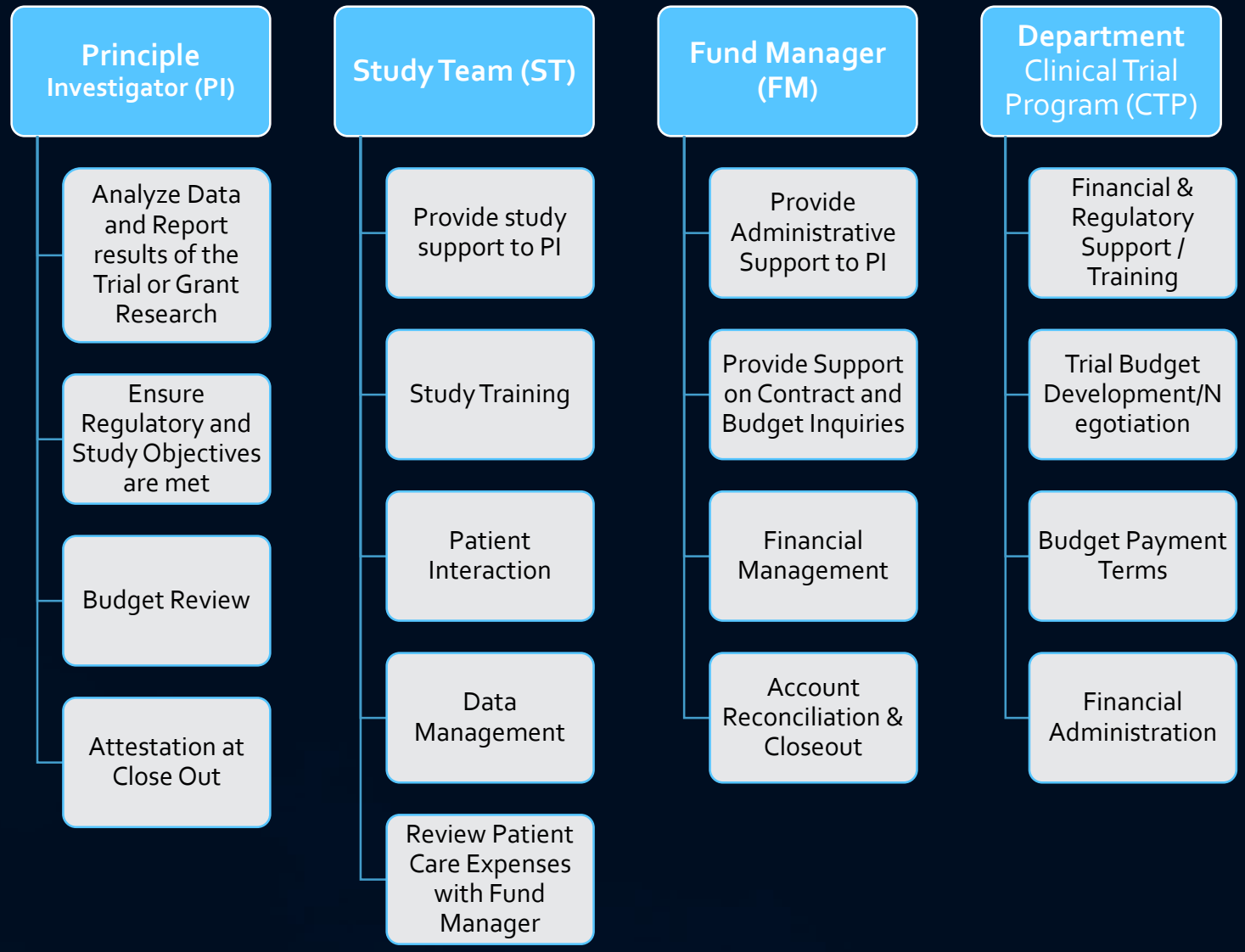
# Clinical Trial - Description

- 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 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.


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
- 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 | 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

- 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.

# UCLA Central Pre-Award Offices & Contacts

- Technology Development Group (TDG)
  - DOM contacts
    - Non-HemOnc: Tara Davidoff (Tara.Davidoff@tdg.ucla.edu)
    - HemOnc: Karla Zepeda (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.

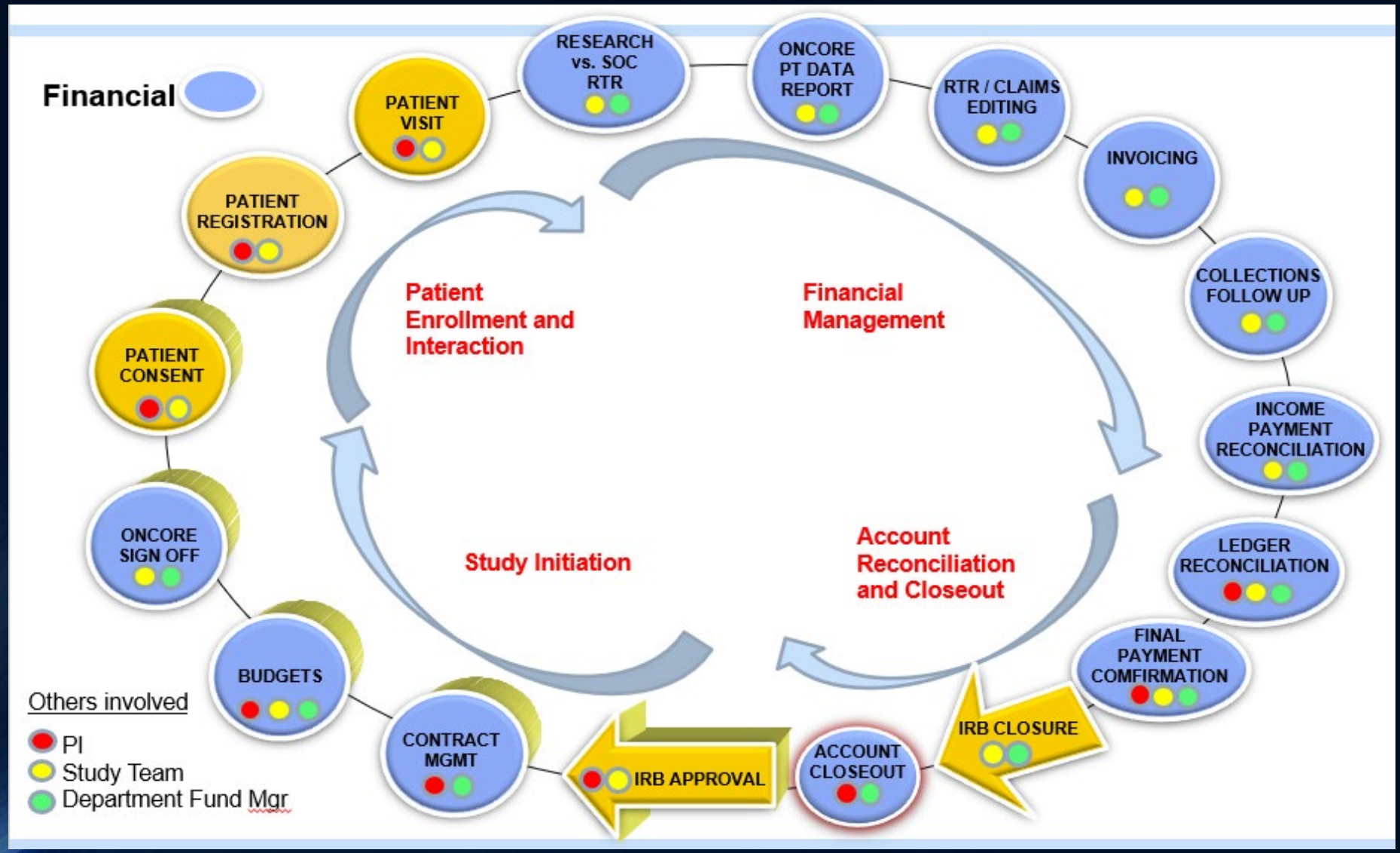
# CT Key Terminology & Acronyms

| | | | | | |
|---|---|---|---|---|---|
| **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 |
| **FM** | Fund Manager | **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 Required Documents Checklist
  - 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 (outside of DOM) services
  - CTSI Clinical Research Coordination Services & Education (CSE) - List of Services
  - Send your email request to CTSI CSE SAT Team (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/RQ1) 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

**Protocol Version: 2.0 December 16, 2019**

| ARM | | | Treatment Phase | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit | Screen 1 | Run in 2 | Cycle 1 3 | Cycle 1 4 | Cycle 2 5 | Cycle 3 6 | Cycle 4 7 | Cycle 5 8 | Cycle 6 9 | Cycle 7 10 | Cycle 8 11 | Cycle 9 12 | Cycle 10 13 | Cycle 11 14 | Cycle 12 15 | End of Study 16 | Total | Follow -up 17 | Follow -up 18 | IPD / IP discontinuation visit | Unscheduled Visit | EXA visit |
| 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 | | Wk58 | Wk64 | | | |
| **Staff Cost** | | | | | | | | | | | | | | | | | | | | | | |
| 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 Coordintor | $ 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 |
| **Procedures/ Assessments** | | | | | | | | | | | | | | | | | | | | | | |
| 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 | $ 210 | | | $ 35 | | |
| SGRQ | | $ 35 | $ 35 | | | $ 35 | | | $ 35 | | | $ 35 | | | $ 35 | $ 35 | $ 245 | | | $ 35 | | |
| ePRO Compliance Check | | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 35 | $ 525 | | | $ 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 | $ 948 | | | $ 158 | | $ 158 |
| **Radiology – Imaging** | | | | | | | | | | | | | | | | | | | | | | |
| Professional Radiology Reading | INVBL | | | | | | | | | | | | | | | | $ - | | | | | |
| MRI/CT | INVBL | | | | | | | | | | | | | | | | $ - | | | | | |
| CD Media Storage | $ 45 | | | | | | | | | | | | | | | | $ 45 | | | | | |
| **Laboratory – Local** | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | $ - | | | | | |
| **Laboratory – Central** | | | | | | | | | | | | | | | | | | | | | | |
| 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 | $ 350 | $ 50 | $ 50 | $ 50 | | $ 50 |
| **Study Drug /Device** | | | | | | | | | | | | | | | | | | | | | | |
| Drug Dispensing Inj Fee | | | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | $ 120 | | $ 1,560 | | | | | |
| Drug Administration /Accountibility Inj Fee (DRUG/Placebo) | | | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | $ 272 | | $ 3,536 | | | | | |
| **Miscellaneous** | | | | | | | | | | | | | | | | | | | | | | |
| 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 |
| **Sub Total** | $ 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** |
| **Overhead 26%** | $ 696 | $ 283 | $ 757 | $ 487 | $ 424 | $ 516 | $ 424 | $ 424 | $ 516 | $ 424 | $ 424 | $ 475 | $ 465 | $ 424 | $ 453 | $ 625 | **$ 7,819** | $ 350 | $ 350 | **$ 431** | **$ 239** | **$ 404** |
| **Total w/ overhead** | $ 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** |

**Anticipated enrollment 8**

| Total of 8 patients | |
|---|---|
| Total Direct | **$240,592** |
| Total Indirect | **$ 62,554** |
| Total Costs | **$ 303,146** |

X: Cost included in budget

* / INVBL: Invoice to sponsor

Q1 / RC1: ROUTINE CARE

**>Invoiceables Schedule 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

| NON-REFUNDABLE FIXED COSTS FOR UCLA | Direct Costs | Indirect Costs | Total | Payable |
|---|---|---|---|---|
| Study Approval Process: Application Preparation & Submission to: IRB, ISPRC, MRSC, CA and Pharmacy | $ 9,000 | $ 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 |
| **Total Non-Refundable Fixed Costs** | | | **$ 28,508** | |

| Items | Direct Costs | Indirect Costs | Total | Payable |
|---|---|---|---|---|
| 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 |



| Procedures | Direct Costs | Indirect Costs | Total | Payable |
|---|---|---|---|---|
| Professional Radiology Reading Fee | $ 390 | $ 101 | $ 491 | 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 |

| Misc | Direct Costs | Indirect Costs | Total | Payable |
|---|---|---|---|---|
| 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. | $ 159 | $ 41 | $ 200 | Upon submission of invoice |
| Ancillary Services CTRC Outpatient Room/Procedure Room (each | $ 150 | $ 39 | $ 189 | Upon submission of invoice |
| Ancillary Services CTRC Staff (each addt'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/Lift/Taxi,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 Capture) – Account Reconciliation

CLINICAL TRIALS

# Financial Management & Administrative Responsibilities

| | |
|---|---|
| **Principal Investigator (PI)** | • Monthly review of expenditures<br>• Approve expenses<br>• Allocation of effort<br>• Provide updates on upcoming occurrences (study on hold, closure, etc.) |
| **Study Team (ST)** | • Enrollment Log(s)<br>• Log participant in OnCore as well as Sponsor EDC systems;<br>• Reconcile patient care billing to patient enrollment in collaboration with Fund Manager<br>• Maintain Study Binder<br>• Data collection |
| **Department Fund Mgr (FM)** | • Process salary and expense transactions<br>• Monthly review of salary & expenditures<br>• Make adjustments/corrections based on salary reports<br>• Update projections<br>• Track patient data and Invoice sponsor<br>• Monthly reconciliation of patient care charges with Study Team & Ancillary Depts<br>• Provide administrative/financial support to PI |
| **Clinical Trial Program (CTP)** | • Financial Training / Support<br>• Budget Development / Negotiation & Budget Payment Terms and Conditions<br>• Account Reconciliation & Closeout support<br>• Administrative Start-up Support |

# Reconciling the Study Visit

- The Research Transaction Reports (RTR) will be distributed by Clinical Research Business Partners (*CRBP*) on a bi-weekly basis for department Study Team/Fund Managers/Charge Reviewers for review and reconcile all charges that have been allocated to research. Data from our OnCore systems will assist you in identifying and reconciling charges. 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

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

# Closing a Clinical Trial Account

The processes should include:

- Completion of a final account reconciliation prior to closure.
- 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.

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)

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
  - CTC&SR (clinicaltrials@mednet.ucla.edu)
  - OCGA (proposals@research.ucla.edu)
  - TDG (Dept Assignments)
  - EFM (Dept Assignments)
  - DOM CTP (DOMCTP@mednet.ucla.edu)
- DOM Clinical Trials Fund Manager Manual Chapters
  - CT Acronyms & Key Terminology
  - CT Required Documents Checklist
  - CT Application Checklist
  - Clinical Research Coordination Services & Education (CSE): List of Services (Study Activation Team & Clinical Research Coordinator)
  - CT Budget Template

# 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!