Introduction to Clinical Trials
Budgeting, Billing & Financial Management

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Class is meant to *supplement* other training, not as all inclusive training. This session will *not* be recorded, but this PowerPoint can be found:

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
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.
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)

<table>
<thead>
<tr>
<th>Sponsors Types</th>
<th>Contracts</th>
<th>Grants Cooperative Agreements</th>
<th>Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Profit</td>
<td>OCGA / DOM DRA*</td>
<td>OCGA / DOM DRA*</td>
<td>OCGA</td>
</tr>
<tr>
<td>For-Profit/Industry</td>
<td>TDG</td>
<td>TDG</td>
<td>CTC&amp;SR</td>
</tr>
</tbody>
</table>

* 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)
    - 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

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

CLINICAL TRIALS
Clinical Trial - Financial Life Cycle

Financial

Patient Enrollment and Interaction

Financial Management

Study Initiation

Account Reconciliation and Closeout

Others involved
- PI
- Study Team
- Department Fund Mgr.

REFUEL

ONCORE PT DATA REPORT

INVOICING

COLLECTIONS FOLLOW UP

INCOME PAYMENT RECONCILIATION

LEDGER RECONCILIATION

FINAL PAYMENT CONFIRMATION

IRB CLOSURE

IRB APPROVAL

ACCOUNT CLOSEOUT

FINAL PAYMENT CONFIRMATION

NEW MARCH 2023

UCLA Department of Medicine - Office of Research Administration
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/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

**UCLA Department of Medicine - Office of Research Administration**

**Study Title:** Placebo-controlled Double-Blind Randomized Parallel Group Multicenter Trial exploring the Effects of Alzheimer's Disease Treatment with HMM in Patients 55-90yrs of Age

### Protocol Version: 2 (December 16, 2019)

<table>
<thead>
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<th>Treatment Phase</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5</th>
<th>Cycle 6</th>
<th>Cycle 7</th>
<th>Cycle 8</th>
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<th>Cycle 11</th>
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<td><strong>Month</strong></td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
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<td>9</td>
<td>10</td>
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<td></td>
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<tr>
<td></td>
<td>May</td>
<td>June</td>
<td>July</td>
<td>August</td>
<td>September</td>
<td>October</td>
<td>November</td>
<td>December</td>
<td>January</td>
<td>February</td>
<td>March</td>
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<tr>
<td><strong>Budget Line Item</strong></td>
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<td>$300</td>
<td>$400</td>
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<td>$600</td>
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<td>$900</td>
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<td>$1200</td>
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<tr>
<td><strong>Total</strong></td>
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<td>$2600</td>
<td>$3900</td>
<td>$5200</td>
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<td>$11700</td>
<td>$13000</td>
<td>$14300</td>
<td>$15600</td>
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</table>

### Principal Investigator
- $100
- $200
- $300

### Co-investigator
- $500

### Other Personnel
- $600

### Core Facility
- $700
- $800
- $900

### Clinical Core
- $1000

**Note:** All amounts are in USD and represent the negotiated budget for the specified treatment phase.

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**Page 1**
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.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Direct Costs</th>
<th>Indirect Costs</th>
<th>Total</th>
<th>Payable</th>
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<tbody>
<tr>
<td>Negotiated Budget</td>
<td>3,000</td>
<td>4,500</td>
<td>7,500</td>
<td>Open to negotiation</td>
</tr>
<tr>
<td>Procedure Fees</td>
<td>3,000</td>
<td>4,500</td>
<td>7,500</td>
<td>Open to negotiation</td>
</tr>
<tr>
<td>Clinical Procedures</td>
<td>6,000</td>
<td>9,000</td>
<td>15,000</td>
<td>Open to negotiation</td>
</tr>
<tr>
<td>Administrative and Institutional Costs</td>
<td>3,000</td>
<td>4,500</td>
<td>7,500</td>
<td>Open to negotiation</td>
</tr>
<tr>
<td>Total Non-Perifiable Fixed Costs</td>
<td>15,500</td>
<td>23,000</td>
<td>38,500</td>
<td>Open to negotiation</td>
</tr>
</tbody>
</table>

UCLA Department of Medicine - Office of Research Administration
Financial Management - Charge Review

CLINICAL TRIALS
Financial Management & Administrative Responsibilities

**Principal Investigator (PI)**
- Monthly review of expenditures
- Approve expenses
- Allocation of effort
- Provide updates on upcoming occurrences (study on hold, closure, etc.)

**Study Team (ST)**
- Enrollment Log(s)
- Log participant in OnCore as well as Sponsor EDC systems;
- Reconcile patient care billing to patient enrollment in collaboration with Fund Manager
- Maintain Study Binder
- Data collection

**Department Fund Mgr (FM)**
- Process salary and expense transactions
- Monthly review of salary & expenditures
- Make adjustments/corrections based on salary reports
- Update projections
- Track patient data and Invoice sponsor
- Monthly reconciliation of patient care charges with Study Team & Ancillary Depts
- Provide administrative/financial support to PI

**Clinical Trial Program (CTP)**
- Financial Training / Support
- Budget Development / Negotiation & Budget Payment Terms and Conditions
- Account Reconciliation & Closeout support
- Administrative Start-up Support
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

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal Investigator (PI)</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - 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 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
  - DOM CTP ([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](mailto:)
  - EFM ([Dept Assignments](mailto:))

- 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!