Clinical Trials
Post-Award: Contract/Award Review

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING
Summary

- Industry Post-Award contract/award
  - Understanding Payment Terms and schedule
  - Contract amendments & NCTE
  - Best practices

- Life Cycle of Contract
CT Key Terminology

• Clinical Trial Agreement (CTA)
  • A legally binding agreement that governs the conduct of a particular study and sets forth the obligations of each party to the agreement. Parties to clinical trial or study agreements include the participating site, the study sponsor, and/or the relevant clinical research organization (CRO).

• Institutional Review Board (IRB)
  • IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

• Case Report Form (CRF)
  • A paper or electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.
Clinical Trial Industry Contract / Award Review Overview

POST-AWARD
Post-Award Contract/Award Start-up – Industry Contracts

- Read through the award/contract after entering an FAU into OnCore. Be sure to understand costs associated to clinical trial budgets, the following are key steps to successfully managing an account:
  - Log in ORA Online Resource Center obtain Award Synopsis
  - To obtain access to the resources on this website, for DOM please submit requests to Raellen Man
  - Assure that all information on the award synopsis matches the Sponsor’s notice of award documentation
  - Human error can be the case at times.
Post-Award Contract/Award Start-up –Industry Contracts

• Review the award/contract payment plan so you may assess what was agreed between sponsor & UCLA for an understanding of when & how billing occurs

• Setup and maintain CT Calc Sheet to track invoicing and payments

• Establish recurring meetings with your Study Teams to discuss:
  • Roles and responsibilities of each Study Team member to support daily operations
  • Study related protocol statuses and updates
  • Study data (i.e. subject enrollment status, subject injury related study visits or unscheduled visits, timelines for data entry in OnCore and Sponsor monitored data), which is also necessary for proper financial management
Payment Terms & Schedule

POST-AWARD
Payment Terms

• As is important with all contract terms, the more detail provided, the more clarity there will be for the all parties.

• Be sure to read over Initial, Ongoing and Final compensation terms and conditions.

• Following up is essential if you want to retain your account in good standing. Perform a follow up on payments after the indicated Net Time.

• There will be times were you will reach out to sponsor to clarify a general statement in the contract.
Payment Terms

- Establish an introduction to determine roles and responsibilities with Sponsor/CRO contact, so both parties can be held accountable for specific tasks.

- High Turnover of Sponsor/CRO: Many face a high staff turnover which can cause delays and risk losing the Sponsor/CRO’s contact and as a result late payment.

- Transparency is essential to minimizing disputes surrounding terms.
Payment Schedule – Common Questions

• Will milestones be paid on completion of Case Report Forms (CRF)?
  • That may mean waiting until the monitor has reviewed the CRF's and sent them into data management for review and payment.

• Will you be paid upon a milestone pending completion of several subject visits?
  • This may delay payments. An ideal schedule will be reimbursed after each subject visit has been performed so that your study account does not run in a high deficit.

• Are there any final payment withholdings?
  • No withholdings is ideal but 5-10% is common for sponsors
  • It may or may not depend on waiting until ALL sites are closed or until the study database has been closed. Pay close attention to this because it can mean that final payments may be delayed for an unreasonable amount of time.
Payment Schedule – Investigator vs Industry

• Payment schedules differ between PI initiated and Industry initiated clinical trials

• Investigator-initiated protocols
  • Sponsors will usually specify certain enrollment based on milestones that must be achieved before payment is made

• Industry/Sponsor-prepared protocols
  • Sponsors normally make payments on a basis of patient visit completion with a payment schedule based on interim milestones of certain treatments/visits achieved (often when CRFs are entered)
  • Other study costs & Invoiceables (i.e. pharmacy fees, advertising/patient recruitment costs, patient stipends, or costs for certain procedures performed as necessary such as pregnancy tests or radiology procedures) may also be paid separately from standard costs per patient
# Budget: Appended Exhibits

## MILESTONE PAYMENTS

<table>
<thead>
<tr>
<th>Milestones</th>
<th>% of Total Funding</th>
<th>Dollar Value</th>
<th>Decreasing Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full execution of the Agreement and IRB approval</td>
<td>20%</td>
<td>$94,012.60</td>
<td>$376,050.40</td>
</tr>
<tr>
<td>Payments will be made monthly based on the number of Study Subject enrolled during the prior month. Total number of Study Subject to be enrolled for the Study is estimated to be 21.</td>
<td>70%</td>
<td>$329,044.10</td>
<td>$47,006.30</td>
</tr>
<tr>
<td>Final Report Received by Sponsor</td>
<td>5%</td>
<td>$23,503.15</td>
<td>$23,503.15</td>
</tr>
<tr>
<td>Receipt by Sponsor of the final version of publication for submission to journals</td>
<td>5%</td>
<td>$23,503.15</td>
<td>0.00</td>
</tr>
<tr>
<td>Total Funding Amount Under this Agreement</td>
<td>100%</td>
<td>$470,063.00</td>
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</table>

## MILESTONE PAYMENTS PER VISIT

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Short Title</th>
<th>UCLA David Geffen School of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Status: N/A</td>
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### Assent

<table>
<thead>
<tr>
<th>Event</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
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</thead>
<tbody>
<tr>
<td>Screening</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Randomization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without Period (Day 1)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Treatment (Days 2-4)</td>
<td>510</td>
<td>100</td>
<td>200</td>
<td>300</td>
<td>400</td>
</tr>
<tr>
<td>Treatment (Days 5-8)</td>
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</table>

<table>
<thead>
<tr>
<th>Principal Investigator</th>
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<th>UCLA David Geffen School of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Status: N/A</td>
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### Clinical Data Collection

<table>
<thead>
<tr>
<th>Event</th>
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<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Exam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History and Chief Complaint</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance Status (ECOG)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Blood Specimen Collection</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab Blood Specimen Processing</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver Function Panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Culture(UCR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug, Nutritional, Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Site Shipping (per Site)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect Costs (IRU+ Fee UCLA Policy)</td>
<td></td>
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</table>

### VISIT TOTAL

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<tr>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1050</td>
<td>655</td>
<td>633</td>
<td>2527</td>
<td>2527</td>
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</tbody>
</table>

### Legend

- **X**: Bundled/Procedure/Service
- **INVIRL, Atestis**: Invoice to sponsor when performed
- **RC**: Routine Cost
Payment Schedule – Pass Through

• Payments Terms surrounding items listed not included in the per subject payments, that either may not occur for all subjects or is needed to maintain study passthrough/invoiceable items

• Invoiceable Administrative (Pass Thru Costs)
  • Administrative services are different from clinical services

• Invoiceable/Conditional related to Subject (Pass Thru Costs)
  • Subject related items performed as needed and not for all subjects

• Invoiceable Ancillary/Dept and 3rd Party Costs (Pass Thru Costs)
  • Supporting UCLA departments and outside companies who provide services
PAYMENTS ARE TRIGGERED WHEN CERTAIN MILESTONES ARE MET. AGREEMENT SHOULD CLEARLY STATE THE ADDRESS SITE NEEDS TO SEND INVOICES FOR THESE MILESTONES.

**IRB Fees:** A non-refundable, local IRB review fee as appropriate, will be reimbursed to institution against invoice in the amounts listed within Attachment 1.

**Storage/Archiving Fee:** A one-time payment in the amount as set forth in the Budget will be reimbursed to the INSTITUTION upon closure of the Study to cover the cost of Record Storage/Archiving Fee related to the Study. This payment will be made upon receipt of invoice from the INSTITUTION.

**Unscheduled Visits:** In the event that a subject has to visit the site for an unscheduled site visit, the INSTITUTION will be reimbursed the amount set forth in the Budget. All unscheduled visits will be entered into the eCRF and will be paid automatically.

**Dry Ice Reimbursement:** The cost of dry ice will be reimbursed to INSTITUTION in the set forth in the Budget upon receipt of invoice from INSTITUTION.

**Pharmacy Set-Up Fee:** A non-refundable, one-time payment in the amount set forth in the Budget will be reimbursed to INSTITUTION upon ICON/SPONSOR. This payment will be made upon receipt of invoices from INSTITUTION.

**Additional Testing, Treatment or Procedures:** INSTITUTION will not be reimbursed for any additional testing, treatment, or procedures not required by the Protocol or specified in this Exhibit A or Attachment 1, unless such additional testing, treatment or procedures are pre-approved by ICON/SPONSOR.

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**UCLA Non-Refundable Start-Up Fee**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DIRECT COSTS</th>
<th>INDIRECT COSTS</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Approval Process</td>
<td>7,500</td>
<td>1,400</td>
<td>9,900</td>
</tr>
<tr>
<td>Mandatory UCLA IRB Submission Fee</td>
<td>2,500</td>
<td>50</td>
<td>2,550</td>
</tr>
<tr>
<td>Pathology and Laboratory Medicine Set-Up Fee</td>
<td>1,000</td>
<td>260</td>
<td>1,260</td>
</tr>
<tr>
<td>Upfront Payment Study Supplies (Printer, Binders, paper, folders, specimen vials etc.)</td>
<td>3,500</td>
<td>910</td>
<td>4,410</td>
</tr>
<tr>
<td>Advertising</td>
<td>5,800</td>
<td>1,456</td>
<td>7,256</td>
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</table>

**Invoicable Administrative Costs:**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DIRECT COSTS</th>
<th>INDIRECT COSTS</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Committee Renewals</td>
<td>1,500</td>
<td>50</td>
<td>1,550</td>
</tr>
<tr>
<td>Amendment/Investigator Brochure without ICF changes</td>
<td>350</td>
<td>11</td>
<td>361</td>
</tr>
<tr>
<td>ICF Translation per page²</td>
<td>5,000</td>
<td>1,300</td>
<td>6,300</td>
</tr>
<tr>
<td>Pre-Screening Per Patient Log</td>
<td>50</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>Study Closure</td>
<td>620</td>
<td>164</td>
<td>784</td>
</tr>
</tbody>
</table>

**Invoicable Costs:**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DIRECT COSTS</th>
<th>INDIRECT COSTS</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copying and Long Term Storage</td>
<td>2,381</td>
<td>610</td>
<td>3,000</td>
</tr>
<tr>
<td>Pharmacy Renewal Fee (Charged Annually)</td>
<td>1,500</td>
<td>390</td>
<td>1,890</td>
</tr>
<tr>
<td>Pharmacy Close-Out Fee</td>
<td>500</td>
<td>130</td>
<td>630</td>
</tr>
<tr>
<td>Study Drug Disposition Fee</td>
<td>50</td>
<td>15</td>
<td>65</td>
</tr>
</tbody>
</table>

**Invoicable / Pass-through pt care items**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DIRECT COSTS</th>
<th>INDIRECT COSTS</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unscheduled Visit</td>
<td>2,000</td>
<td>520</td>
<td>2,520</td>
</tr>
<tr>
<td>Pregnancy Test</td>
<td>25</td>
<td>7</td>
<td>32</td>
</tr>
<tr>
<td>Screen Failures²</td>
<td>1,700</td>
<td>442</td>
<td>2,142</td>
</tr>
</tbody>
</table>

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UCLA Department of Medicine - Office of Research Administration
Payment Terms & Schedule - Other

• What to do when billed items are NOT in the contracted budget

1. Contact your Study Team and ask them if the item is study related.
2. If so, retain a written email from Sponsor/CRO confirming reimbursement for such items then bill sponsor at approved DOM CTP rate including overhead.
3. You may want to revisit with Study Team to see if contract needs to be amended to include invoiceables/reimbursements
   • Note: Do not take actual rate and bill sponsor unless sponsor is nonprofit.

• Retain back-up for 3rd party expenses

• If contract payment terms stipulate back-up for 3rd party invoices, this means services may have been outsourced. File and save 3rd party invoices to attach as back-up when invoice gets submitted to sponsor
   • i.e. ICF translations, outside labs, etc.
CT Contract Amendments & No Cost Time Extensions

POST-AWARD
Contract Amendments

• An amendment changes the terms of a previously executed agreement. Adding, removing or changing a clause or an exhibit in the agreement. Such modifications could arise due to change in the study budget arising from a protocol amendment, changes in legislation or they could simply arise from human error.

• Multiple amendments are necessary to optimize study results and ensure patient safety and their ethical treatment.

• Amendments for Clinical Trial Agreements (CTA) may be required for various reasons.
  • Please refer to the Clinical Trial Contract Checklist to see which Minimum Documents are required for your CTA amendment. Submit all documents to the CTC&SR Intake Team or TDG.

• It is essential for Study Teams to inform and update Fund Managers on any progress or changes that involve amendments.
Contract Amendments

• **Common types of amendments:**
  • Sponsor initiated *protocol amendments* that change or add items that affect budgeted amounts
  • UCLA initiated *budget amendments* that change or add items that affect the budgeted amounts
  • Sponsor initiated *changes to CRO* to ensure:
    • The CTA names the correct legal entity, which allows UCLA to send invoices and legal notifications to the appropriate entity
    • No conflict of interest exists between the new Sponsor and the PI and anyone on the study team
Contract Amendments

• **PI Change:**

• It takes less time to finalize a PI change because contract language and budget are most likely not going to change during this amendment

• When your Study Team indicates a **PI change** they must:
  • Notify sponsor of PI change
  • Submit IRB with new PI indicated and update study related documents
  • Fund Managers will route all internal forms as for new study
Contract Amendments

• Protocol Amendment vs. Contract Amendment
  • Multiple protocol amendments can be submitted for changes to IRB prior to executing a contract amendment change
    • I.e. Protocol amendment reflects version 4 and Contract amendment reflects protocol amendment (PA) 1

• A Contract Amendment during mid-activation indicates that a contract is actively being negotiated
  • In good faith, subjects may continue to be seen during pending amended procedures based on IRB approval
No Cost Time Extension (NCTE)

• A NCTE can be processed *without* having to amend the contract if:
  • 1) there is no hard End Date written into the contract
  • 2) there are no changes to the protocol, IRB, budget, or PI

• For NCTE, submit the following Documents to **CTC&SR Intake Team** or **TDG**
  • **NCTE Request Form**
  • Current IRB Approval Notice
  • New extended end date
  • For TDG, include revision of internal budget (extending years)

• Note: If a Contract Amendment is under review when NCTE request is received, the NCTE will be processed with the amendment once Amendment Minimum Minimum Documents have been received
Tips and Best Practices

• When establishing contact with Sponsor/CRO, it is always good to ask for a supervisor contact in case of turnover.

• At times sponsors will utilize their own budget template in contracts listing only total amounts (lacking detail of how costs are allocated).

• Keep an internal budget/matrix in study file to specify which amounts are applicable to salaries as well as identify if items are billable to study or insurance.

• If a detailed Industry/For-Profit budget is not immediately accessible/available (not filed), go into your Financials Console in OnCore System to obtain the final legible version of the contracted budget. If not in System, ask the negotiating party for an internal copy of the detailed budget outlining cost allocation. You will need this during reconciliation.
Tips and Best Practices

• Understand study payment terms for effective and efficient invoicing
  • Usually payment terms are located at the very beginning or end of contract
  • Fully executed date is when the contract was executed

• When reviewing contract amendments, be sure to understand what was agreed to in prior executed contracts
  • Note that amendments may impact performance and cost

• Communicate effectively with Study Team and schedule regular meetings

• There at times will be unfamiliar words in the contract. Feel free to reach out to DOM CTP for support.
Links from Today’s Class

- DOM Clinical Trials Fund Manager Manual Chapters
  - CT Acronyms & Key Terminology
  - CT Calc Sheet
  - CT Industry Budget - Invoiceable Salary Related Costs
  - CT Common Department/Ancillary Items
  - CT New/Amended Study Notice From Study Team to Fund Manager
  - CT No Cost Time Extension (NCTE)
    - NCTE Request Form
- Contacts
  - CTC&SR Dept Assignments
  - TDG Dept Assignments
  - DOM Clinical Trial Program – DOMCTP@mednet.ucla.edu
Survey Link
https://forms.gle/QaMyquTuMkTkNDEj1k8

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!