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

Clinical Trials

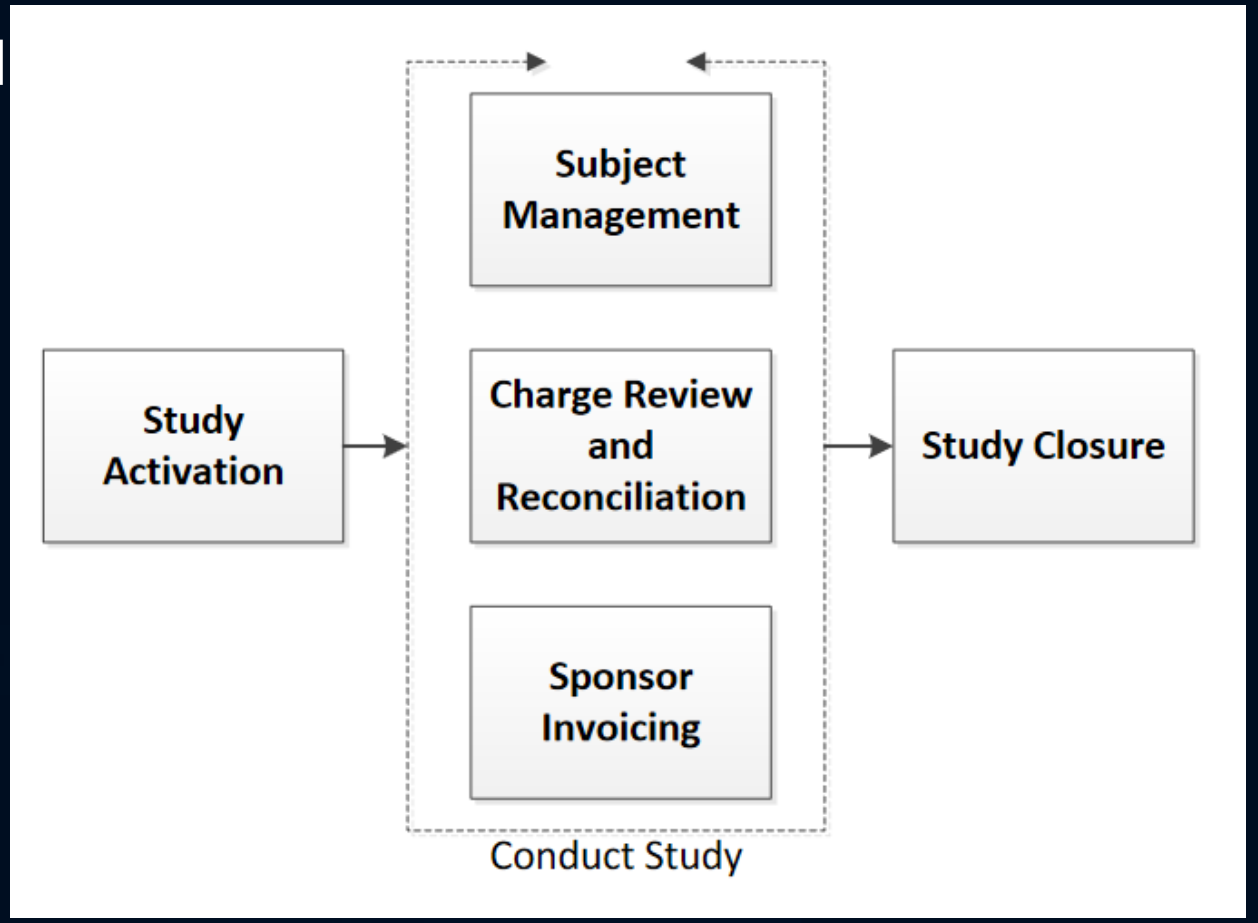
Post-Award: Contract/Award Review

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

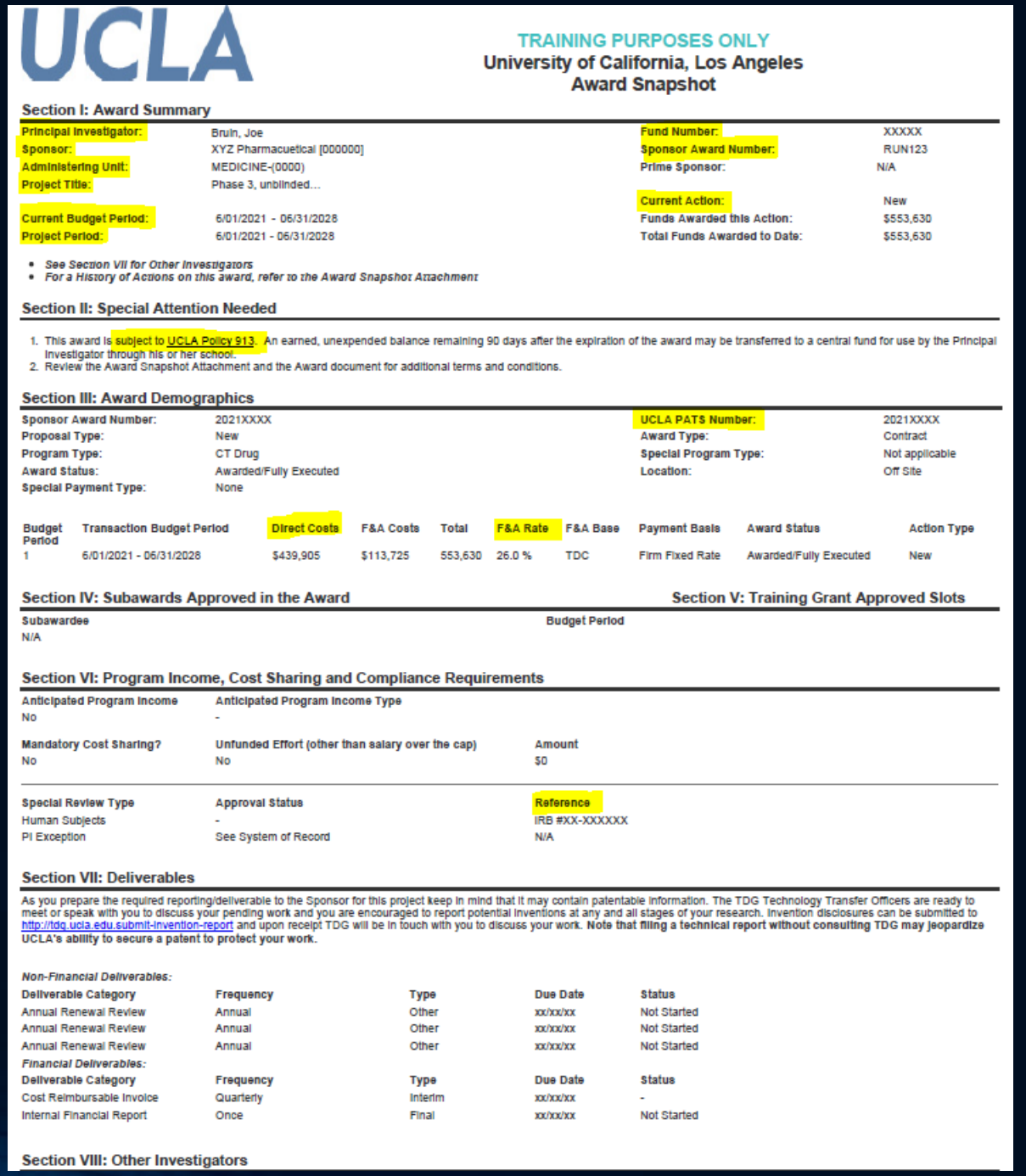
- Clinical Trial Agreement (CTA)
  - A legally binding agreement that governs the conduct of a particular study and sets forth the obligations of each party to the agreement. Parties to clinical trial or study agreements include the participating site, the study sponsor, and/or the relevant clinical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



UCLA

TRAINING PURPOSES ONLY
University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Bruin, Joe	Fund Number:	XXXXX
Sponsor:	XYZ Pharmaceutical [000000]	Sponsor Award Number:	RUN123
Administering Unit:	MEDICINE-(0000)	Prime Sponsor:	N/A
Project Title:	Phase 3, unblinded...		
		Current Action:	New
Current Budget Period:	6/01/2021 - 06/31/2028	Funds Awarded this Action:	$553,630
Project Period:	6/01/2021 - 06/31/2028	Total Funds Awarded to Date:	$553,630

- *See Section VII for Other Investigators*
- *For a History of Actions on this award, refer to the Award Snapshot Attachment*

Section II: Special Attention Needed

1. This award is subject to UCLA Policy 913. An earned, unexpended balance remaining 90 days after the expiration of the award may be transferred to a central fund for use by the Principal Investigator through his or her school.
2. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	2021XXXX	UCLA PATS Number:	2021XXXX
Proposal Type:	New	Award Type:	Contract
Program Type:	CT Drug	Special Program Type:	Not applicable
Award Status:	Awarded/Fully Executed	Location:	Off Site
Special Payment Type:	None		

Budget Period	Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type
1	6/01/2021 - 06/31/2028	$439,905	$113,725	553,630	26.0 %	TDC	Firm Fixed Rate	Awarded/Fully Executed	New

Section IV: Subawards Approved in the Award — **Section V: Training Grant Approved Slots**

Subawardee	Budget Period
N/A	

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	$0

Special Review Type	Approval Status	Reference
Human Subjects	-	IRB #XX-XXXXXX
PI Exception	See System of Record	N/A

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Annual Renewal Review	Annual	Other	xx/xx/xx	Not Started
Annual Renewal Review	Annual	Other	xx/xx/xx	Not Started
Annual Renewal Review	Annual	Other	xx/xx/xx	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Cost Reimbursable Invoice	Quarterly	Interim	xx/xx/xx	-
Internal Financial Report	Once	Final	xx/xx/xx	Not Started

Section VIII: Other Investigators

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

A-1. General Terms. Payee (hereinafter defined) will be compensated as outlined on Attachment B (Financial Arrangements Worksheet) for Trial Subjects enrolled in the Trial in accordance with the Protocol. No compensation will be available for Trial Subjects enrolled in the Trial in violation of the Protocol.

A-2. Payment Terms. Payments for each Trial Subject will be made monthly and based on CRF data entered by Institution supporting enrolled Trial Subject visitation. Payments will be made for completed visits and treatment related costs in accordance with Attachment B (Financial Arrangements Worksheet), unless otherwise noted in the Agreement. For each payment, including any Screen Failures (as defined below) that may be payable under the terms of this Agreement, Payee will be paid the total amount earned, less 5%, for the Final Payment (hereinafter defined). Monitoring will occur based on site enrollment and completion of data entry. Payee should submit any final invoices within sixty days (60) calendar days after the site close-out visit. Payee will have sixty (60) calendar days after the date of the site close-out visit to dispute any payment discrepancies or missing payments.

A-3. Pass-through payments from Sponsor. Payments due under this Agreement are pass-through payments from Sponsor that will be sent after such payments are received by Syneos Health from Sponsor. Syneos Health shall have no liability for any failure to make payments if required funding is not provided to Syneos Health in advance by Sponsor.

A-4. Non-Procedural Costs. Payee will be paid for additional non-procedural costs as set forth in Attachment B (Financial Arrangements Worksheet). To request payment for such costs, Payee will remit an itemized invoice to Sponsor through Syneos Health. Any non-procedural pass-through expenses will be invoiced up to the maximum amounts shown in Attachment B (Financial Arrangements Worksheet).

A-5. Final Payment. The Final Payment will be paid once: all CRFs and other outstanding Trial Data and Biological Samples have been completed and received; all Sponsor Drug is returned at Sponsor's/Syneos Health's expense; and all close out issues are resolved and procedures completed, including final IRB notification. Sponsor or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any. Syneos Health shall make final payment to Institution within thirty (30) calendar days of Institution's site close out visit.

A-6. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria set forth in the Protocol and is thus not eligible for enrollment into the Trial. Screen Failures will be reimbursed as outlined in Attachment B (Financial Arrangements Worksheet).

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

Payments will be submitted with correspondences and supporting documentation date & description of services provided (subject#, visit/invoiceable procedure, date of service, amount) or UCLA invoice # referenced on check submissions with PI name, Sponsor, protocol#, IRB#.

Updates to Payee address and banking information can be submitted in writing to Syneos Health but no amendment to this Agreement shall be required. Each payment must reference the PI name, Sponsor name and protocol #.

A-8. Invoices and Payment Related Queries. All invoices must be forwarded to the following as instructed:

Attn. Investigator Payment Department
Syneos Health, LLC
1030 Sync Street
Morrisville, NC 27560 USA
Re: Project Code 1009191
E-mail: SM_InvestigatorPayments@SyneosHealth.com

All payment related queries may be directed to:

SM_InvestigatorPayments@SyneosHealth.com

Except as set forth in section A2 above, all other payments shall be invoiced. Each invoice must contain: (1) Sponsor's name, (2) Protocol number, (3) project code, (4) Principal Investigator's name, and (5) a summary of the reimbursement to be made in compliance with the Attachment B (Financial Arrangements Worksheet).

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

Total Funding Amount Under this Agreement	$470,063		
Milestones	**% of Total Funding**	**Dollar Value**	**Decreasing Value**
Full execution of the Agreement and IRB approval	20%	$ 94,012.60	$ 376,050.40
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.	70%	$ 329,044.10	$ 47,006.30
Final Report Received by Sponsor	5%	$ 23,503.15	$ 23,503.15
Receipt by Sponsor of the final version of Publication for submission to journals	5%	$ 23,503.15	$ 0.00
Total Funding Amount Under this Agreement	100%	$ 470,063.00	

MILESTONE PAYMENTS *PER VISIT*

Principal Investigator:	Bruin, Joe	Tab 1 of 3		UCLA David Geffen School of Medicine	
Short Title:	PINE				
IRB#:	XX-XXXXX				
					Status: New
Arm:1					
	Screening	**Randomization**	**Washout Period**	**Treatment (first 3 days)**	**Treatment (days 4 and on)**
			(<6hrs)		
	V1	V2	V3	V4	V5
Principal Investigator	200	200	200	500	700
Study Coordinator	300	200	200	800	600
Data Manager	200	150	150	200	200
Informed Consent	300				
Physical Exam	220			220	220
History and chart review	X				
Performance Status (ECOG)	X				
Adverse Events	X		X	X	X
Conmeds	X		X	X	X
Questionnaires	105				
Local Lab Specimen Collection	50			50	50
Lab Specimen Processing	100			100	100
Liver Function Panel	25			25	25
Pregnancy (Urine) [AN]	INVBL				
Drug Accountability/ Administration				RC1	RC1
Drug				RC1	RC1
Pharmacy Site Shipping (per Site)				150	150
Hospitalization	RC1	RC1	RC1	RC1	RC1
Direct Costs	1500	550	550	2045	2045
Indirect Costs (26% Per UCLA Policy)	390	143	143	532	532
VISIT TOTAL	**1890**	**693**	**693**	**2577**	**2577**
Calendar Foot Notes					

Legend	
X	Bundled Procedure-Service
INVBL, P, Asterisk (*)	Invoice to sponsor when performed
RC 1	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

Budget: Initial & Conditional/Pass Through Items

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 nonrefundable, local IRB review fees 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 I 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 invoice 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.

UCLA Non-Refundable Start-Up Fee			
ITEM	**DIRECT COSTS**	**INDIRECT COSTS**	**Subtotal**
Study Approval Process:	7,500	1,950	9,450
Mandatory UCLA IRB Submission Fee	2,500		2,500
Pathology and Laboratory Medicine Set- Up Fee	1,000	260	1,260
Upfront Payment Study Supplies (Printer, Binders, paper, folders, specimen vials etc)	3,500	910	4,410
Advertsiement	5,600	1,456	7,056
			24,676
Invoiceable Administrative Costs:			
Annual Committee Renewals	1,500	390	1,890
Amendment/Investigator Brochure without ICF changes	350	91	441
ICF Translation per page[A]	5,000	1,300	6,300
Pre-Screening Per Patient Log	50	13	63
Study Closure	630	164	794
Invoiceable Costs:			
Copying and Long Term Storage	2,381	619	3,000
Pharmacy Renewal Fee (Charged Annually)	1,500	390	1,890
Pharmacy Close-Out Fee	500	130	630
Study Drug Destruction Fee	50	13	63
Invoiceable / Passthrough pt care items			
Unscheduled Visit	2,000	520	2,520
Pregnancy Test	25	7	32
Screen Failures[C]	1,700	442	2,142

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 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/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!