Budgeting and Negotiating Clinical Trials: A Post-Award Perspective

NCURA Region IV Spring Meeting 2013

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Session Details

Objectives: Learn the key administrative elements of a clinical trial agreement and be able to develop management tools and reduce risks areas.

Speakers:

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Budgeting vs. Billing Activities

Pre-Award: Budgeting

- Developing budget grid
- Identifying study staff
- Obtaining CMS approvals *(if applicable)*
- Setting rates internally
- Negotiating with Sponsor
- Creating charge codes for research services
- Billing Grid

Post-Award: Billing

- Invoiceables
- Research registrations
- Reviewing subject bills
- Processing charge corrections
- Tracking subject enrollment
- Allocating time/effort for personnel
- Manage research account(s)
- Invoicing sponsor
- Cash management

TOOLBOX

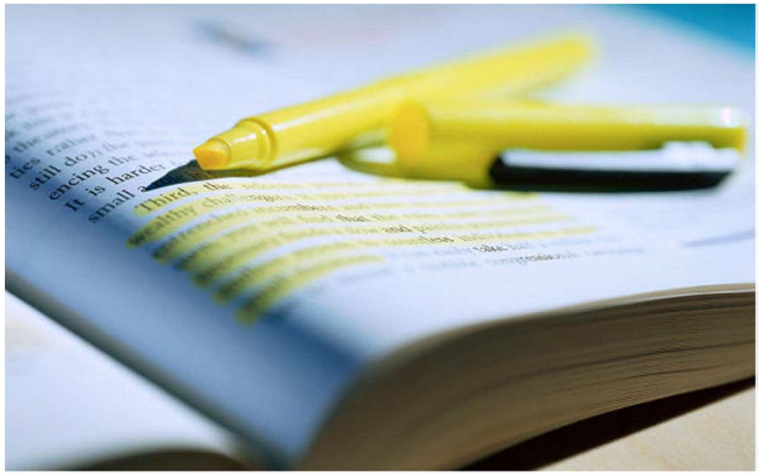
- Items Completed During **Pre-Award** Process:
  - Clinical Trial Agreement
  - IRB Approval
  - Informed Consent Form
  - Recruitment plan
  - Payment Terms & Budget
  - Billing Grid

- Items To Develop for **Post-Award** Activities:
  - Invoice template for the study
  - Study binder
  - Accounts receivable log
  - Accrual projections
  - Enrollment log
  - Identify action items

Clinical Trial Agreement

Key elements for an administrator

- Period of performance
  - Is an end date stated?
- Notices
- Termination
- Order of precedence
- Subject injury
- Payment Terms
- Milestones
- Budget Exhibit
  - Per patient vs. line item
  - Automatic vs. Invoiced



DEVELOP A BUDGET BREAKDOWN

Total Per Patient:	$	9,065
Maximum Accrual:	$	15
Maximum Per Patient Totals:	**$**	**135,975**
Initiation and Maintenance Fees		
Start-up Fee (non refundable)	$	3,250
Screen Failures	$	325
Protocol Amendments	$	325
Reconsenting Subjects	$	195
SAE Reporting (per report)	$	98
On-Site Monitoring Visit (per day)	$	325
Advertising/Recruitment	$	1,300
Close-Out Fee (includes data retention)	$	2,600
Subtotal Initiation & Maintenance:	$	**8,418**
IRB & Regulatory Fees		
IRB and Regulatory Submission Fee	$	5,000
IRB Revision/Renewal Fee (per review)	$	750
Subtotal IRB & Regulatory Fees:	$	**5,750**
SUBTOTAL -- NON-PATIENT Fees	**$**	**14,168**
TOTAL	**$**	**150,143**

Sample Enrollment Log

- Be aware of PHI
  - Privacy rules and human subject protection training (i.e. CITI)
  - Authorized study personnel
  - Password protect files, limit point of access
  - Key control document

Subject ID #	MRN	NAME	Screening	Randomize	Base	10 Day Follow-up
MSU-01-001	00293	Doe, Jane	1/4/13	1/8/13	1/10/13	1/20/13
MSU-01-002	00740	Smith, John	2/9/13	2/13/13	2/15/13	2/25/13

Sample Log Modifications

- Include additional data elements for other team members
- Maintain (or try) one single file for dual purposes
  - Minimize entry errors
  - Improve processes
  - Set entry expectations
    - Enrollment: entry same day
    - Stipend reconciliation: enter monthly

Subject ID #	MRN (AMC)	MRN (Hosp)	NAME	CONSENT DATE	Stipends Issued - W9 on file?	Screen	Rand.	…
MSU-01-001	00293	12364	Doe, Jane	1/4/13	Y	1/4/13	1/8/13	
MSU-01-002	00740	12790	Smith, John	2/9/13	Y	2/9/13	2/13/13	

Crosswalk for invoices

Tip! Complete W-9 at consent

Include consent date for compliance AND metrics

IT STARTS AT REGISTRATION

- Key elements for success
  - Timing – same day!
  - All parties: billing office, PI, Dept, other key personnel
  - Consistency
  - Documented: EMR, form, email, etc.
    - Phone calls okay, but follow-up with email (same day)
  - Implement bill hold
    - Control element
    - Refer to billing grid to designate research services
    - Ensure proper charge codes are being used
    - Set a turnaround time goal (keep the billers happy)

Monthly Review of Study Activity

Key element

- Each month a designated member of the study team should review the **detailed** charges for each date of service
  - Invoice review for each patient enrolled
  - Stay apprised of changes made to the consent form
  - Cancer studies carry the most administrative burden

- Master subject lists
  - Make sure the billing office knows **who** is on a trial and **what** items can be billed. Provide them with the billing grid!
  - Clinical Trial Management System (CTMS) – **ideal**
    - Modifiers (i.e. Q0 & Q1)
    - Diagnosis code: V70.7

Monthly Review (cont.)

- Refer to Billing Grid
  - Crosswalk tool for coordinator, administrator and clinical billing staff
  - Billing grid legends tend to vary

- Verify accuracy of charges
  - Date(s) of service
  - Are SOC items being charged to research account?
  - Are research items being charged as SOC?
  - What is missing? Are the right codes being used?
  - Useful to have pre-award & post-award activities completed by the same individual

Cash Management

- CTA will define the payment terms for the project

- Payment terms may differ on the same study, for different activities
  - Case Report Forms (CRFs)
  - Milestones
  - Other automatic payments
  - Invoiceable Items (below the line)
    - Study coordinator is usually responsible for identifying when these are triggered

- Proactive cash management approaches help minimize deficit spending
  - Set payment due term upfront (i.e. net 45 days)
  - Include "Past Due" items on future invoices

Accounts Receivable

- Monitor payments owed and received
- Ensure line item costs are billed as negotiated
- Review payment terms in the Agreement
  - Payment methods, frequency, contact information
  - Milestones and report deadlines
- Create accounts receivable tracking sheet

A/R Details						Receipt Details		
Description	Invoice #	Invoice Date	FY Issued	Day Aging	Amount Invoiced	Amount Recd	Cleared A/R	Check Number
Start-Up Fee, IRB, Reg Prep	60764-01	11/25/12	FY12		$7,500	$7,500	Yes	577821
Subject#: MSU-01-001 Baseline	60764-02	1/10/13	FY13		$4,565	$4,565	Yes	952181
Subject#: MSU-01-001 Randomize	60764-03	2/15/13	FY13	50	$1,265	$265	No	952310
Subject#: MSU-01-002 Baseline	60764-04	3/20/13	FY13	17	$4,565		No	
TOTAL	4				$17,895	$12,330		

Tip! Assign sequentially

BE AWARE OF PARTIAL PAYMENTS

Sponsor may only pay a portion of an invoice, due to:

- Payment withholds until end of study
- Prorated payment due to study milestones
- CRF issues: incomplete, delayed, **unverified**
- Not all study procedures may have been performed
- Subject withdrawal

A/R Details						Receipt Details		
Description	Invoice #	Invoice Date	FY Issued	Day Aging	Amount Invoiced	Amount Recd	Cleared A/R	Check Number
Subject#: MSU-01-001 Randomize	60764-03	2/15/13	FY13	50	$1,265	$265.00	No	952310

Closeout Checklist

- Review CTA terms for closeout procedures
- Verify study status
  - Sponsor's letter indicating closeout
  - IRB termination letter
- Accounts Receivable
  - Verify all payments have been received
- Payables
  - Time/effort for research personnel
  - Patient care costs
  - IRB fees
  - Vendor payments
  - Pass-through invoices
  - Remove encumbrances
- Balance Resolution

Clinical Trial Agreements: Post Award Perspective

Post Award Contract Considerations

Once the Clinical Trial Agreement is executed, there are subsequent agreements that you should look out for, such as:

- Subcontracts
- Amendments
- Terminations
- Notices
- Study Related Injuries

SUBCONTRACTS

- A subcontract is a third-party organization performing a portion of an Institution's research project or other sponsored programs
  - Common for multi-site trials Sponsored by other Academic Medical Centers
- Institution is responsible for the monitoring its subcontracts
- Institution must ensure the terms of its subcontracts are in compliance with relevant laws, regulations, and the terms and conditions of the prime agreement

AMENDMENTS

Amendments are the most common subsequent agreements. Some scenarios that require amendments, may include:

- PI changes
- No cost extensions
- New reporting requirements
- Budget amendments
- New CRO assignments
- Protocol Changes

TERMINATIONS

- Clinical trials may be terminated for various reasons, such as:
  - Material Breach by either party
  - Enrollment
  - Bankruptcy

- CTA termination clause should ensure Sponsor pays for **non-cancelable** obligations.
  - Sponsor shall reimburse Institution for all actual costs and non-cancelable obligations reasonably incurred and irrevocably committed up to the date of termination and for any expenses related to maintaining subjects in the Study to the extent they cannot be safely withdrawn.

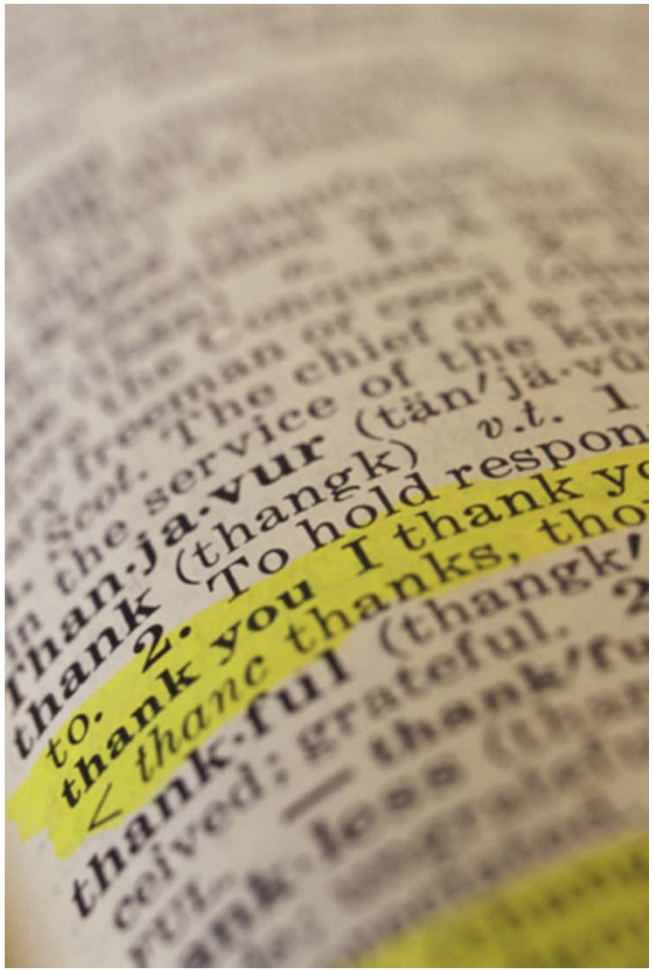
NOTICES

- Acquisitions
- Assignments
- Name changes
- Contact Updates
- Debarment
  - Institution required to notify Sponsor of debarment.
- PI transfer
- Subject related injuries
  - Coordination with PI, Research Administrator, and Contracts Officer
  - Contracts Officer reviews the CTA for the Subject Injury clause

In Summary

- Clearly document
- Communication
- Registration, Registration, Registration!
- Billing compliance
- Be the patient's advocate
  - The informed consent governs
- Use technology
- Don't under estimate the benefit of setting up your clinical trials in a consistent manner
  - REDUCE the administrative burden on staff

QUESTIONS?



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