



OFFICE OF THE VICE CHANCELLOR
FOR RESEARCH

Research Administrators Monthly Meeting October 2018

**Peggy Diskin, Associate Director (Proposals)
Office of Research Services**

Agenda

- Announcements
- Clinical Trial Budget Basics
- Questions/Discussion



Announcements

- Proposal Team Contacts
- Thank you Beth!



Clinical Trial Budget Basics

Identify the Components of a Clinical Trial Budget

Identify the hidden costs

Initial Contact from Sponsor

- The sponsor reaches out to potential sites to determine interest and feasibility for conducting a trial
- A pre-study questionnaire may be requested to summarize potential for patient recruitment, staff availability, and existence of needed equipment

Where Do I Start?

What you need:

- The Protocol
 - schedule of events
- The sponsor draft informed consent
- The sponsor draft budget
- The sponsor draft contract

Schedule of Events

Epidural Neuromodulation for Spinal Cord Injury
Protocol <#>

Version <1.66>
<03/07/2017>

Table 2

	Screening	Enrollment	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15
Procedures															
Spinal Cord Stimulator Implantation		X													
Demographics	X														
General Health History	X														
Epidemiology/Environmental History	X														
History of Disease/Injury Event	X														
Physical Examinations	X	X	X			X			X			X			X
Vital Signs and Other Body Measures															
Vital Signs and Tests	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Laboratory Tests	X														
Spinal Imaging / Spinal Cord Imaging	X														
Treatment / Intervention Data															
Assistive/Mobility Devices & Orthosis	X														
Falls Diary	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
NBSS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
NBDS	X					X									X
Rehabilitation Therapies	X														
Surgical and Procedural Interventions	X														
Other Investigational Treatments	X														
Home Training			X	X	X	X	X	X	X	X	X	X	X	X	X
Neurological Outcomes															
Classification of SCI	X														
Modified Ashworth Scale	X		X			X			X			X			X
NINDS Myotatic Reflex Scale	X														
Electrodiagnostics															
Brain Motor Control Assessment	X		X	X	X	X	X	X	X	X	X	X	X	X	X
Device electrode mapping		X	X			X			X			X			X
Standing Training Assessment			X			X			X			X			X
Functional Outcomes	X														
Autonomics															
Autonomic Screening	X														
Autonomic Assessments			a			a			a						
Sympathetic Skin Responses			a						a						
Cognitive			a			a			a						
Pain	X		X			X			X			X			X
Psychological	X		X			X			X			X			X
Quality of Life	X		X			X			X			X			X
Sleep	X		X			X			X			X			X

Items are grouped according to the major categories of 7.1.1 in blue. Categories containing elements administered at different times in the study are expanded and grayed out. 'X' represents mandatory assessments for all subjects. 'a' represents assessments for subjects selected to undergo autonomics protocol.

Coverage Analysis

Microsoft Word ribbon: Home, Insert, Page Layout, Formulas, Data, Review, View, Add-Ins, Acrobat. Ribbon options include Themes, Colors, Fonts, Effects, Margins, Orientation, Size, Print Area, Breaks, Background, Print Titles, Width: 1 page, Height: 1 page, Scale: 18%, Gridlines, Headings, View, Print, Sheet Options, Bring to Front, Send to Back, Selection Pane, Align, Group, Rotate, Arrange.

Worksheet A2 content:

1 Study Title:
 2
 3 Protocol numbers
 4 Principal Investigator:
 5 Coverage Analysis Version Date:
 6
 7 **This Coverage Analysis is intended as a general guideline for use in determining which items and services are billable to Medicare/third party payers based upon current benefit policies, coverage determinations, coverage decisions, and physician determinations. All items and services designated as billable must be supported by medical necessity.**

Items and Services	Protocol Location	CPT/HCPCS Codes	Q100 Modifiers	Prescreening	Screening	Treatment Phase (cycle=28 days)			Post treatment			Comments	Biller Summary
					≤35 Days Prior to Randomization	Cycle 1 Day 1	Cycles n Day 1 (±2 days)	Every 16 weeks (Starting on CID1)	End-of-Treatment	Safety Follow-up	Survival Follow-up*		
Should Dx Code V70.7 (and Condition Code 30, where applicable) appear on the claim?					No	No	Yes	Yes	Yes	No	Yes		
Time & Effort													
Informed Consent	Prot. P. 83	N/A	No	NA	NA								This is not a billable item or service. Non-billable; research related.
Inclusion/Exclusion Criteria	Prot. P. 83	N/A	No	NA	NA								This is not a billable item or service. Non-billable; research related.
Randomization	Prot. P. 83	N/A	No	NA	NA								This is not a billable item or service. Non-billable; research related.
Adverse Events ¹	Prot. P. 84	N/A	No	NA	NA	NA	NA	NA	NA	NA			This is not a billable item or service. Non-billable; research related.
Concomitant Medications ²	Prot. P. 84	N/A	No	NA	NA	NA	NA	NA	NA	NA			This is not a billable item or service. Non-billable; research related.
Medical Resource Utilization	Prot. P. 83	N/A	No			NA	NA						This is not a billable item or service. Non-billable; research related.
Progression on First Subsequent Therapy	Prot. P. 84	N/A	No								NA ¹		This is not a billable item or service. Non-billable; research related.
FACT-P and EQ-5D	Prot. P. 84	N/A	No			NA	NA		NA		NA ¹		This is not a billable item or service. Non-billable; research related.
Study Drug Compliance	Prot. P. 83	N/A	No										This is not a billable item or service. Non-billable; research related.
Evaluation & Management Services													
Physical Examination	Prot. P. 84	99201 - 99205; 99211 - 99215 G0463	Q1 or No		R	N	N		N				Per Institutional Policy, any item or service performed at baseline/screening is not billable unless medical necessity is documented. Billable during treatment and post-treatment.
Medical/Oncological History	Prot. P. 83	N/A	No		R								This is not a separately billable item or service. Not separately billable; included in physical exam.
ECOG	Prot. P. 83	N/A	No		R	N	N		N				This is not a separately billable item or service. Not separately billable; included in physical exam.
Vital Signs	Prot. P. 84	N/A	No		R	N	N		N				This is not a separately billable item or service. Not separately billable; included in physical exam.
Labs													
PSA	Prot. P. 83, 85	84153	No	R ¹									Per Institutional Policy, any item or service performed at baseline/screening is not billable unless medical necessity is documented. Note: Per NCD 190.31, PSA is a marker used to follow the progress of prostate cancer once a diagnosis has been established.
Venipuncture	N/A	36415 or 36592	No	R									This item is provided in conjunction with research laboratory testing. To the extent that the laboratory test is covered, so is the venipuncture. To the extent that the laboratory test is covered, so is the venipuncture.
Central Labs													
CBC with and Platelets	Prot. P. 83	36415 or 36592	No		CL	CL	CL		CL				All laboratory assessments will be performed by a Non-billable; sent to central laboratory.

Ready | Study Info | Billing Grid | Average: 4732501.333 | Count: 256 | Sum: 14197504 | 70% | 8:08 AM 2/6/2015

Sponsor Draft Budget

Procedures	Total Quantity	Selected Cost	Visit 1 - Screening	Visit 2 - Day 1	Visit 3 - Week 1	Visit 4 - Week 4	Visit 5 - Week 8	Visit 6 - Week 12	Visit 7 - Week 16	Visit 8 - Week 20	Visit 9 - Week 24	Visit 10 - Week 28	Visit 11 - Week 32	Visit 12 - Week 36	Visit 13 - Week 40	Visit 14 - Week 44	Visit 15 - Week 48	Visit 16 - Week 52 (End of Study)	Total	
Informed Consent	1.00	150.00	150.00																150.00	
Complete Physical (Med Hx, Height,	1.00	215.00	215.00																215.00	
Comp. Follow-Up Visit w Phys/Vitals	1.00	180.00																180.00	180.00	
Vital Signs	13.00	25.00		25.00		25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	325.00	
ECG	3.00	125.00	125.00					125.00											125.00	375.00
Review Concomitant Medications	16.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	560.00	
Intravitreal injection of REGN2176-3 Or	13.00	400.00		400.00		400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	400.00	5,200.00	
BCVA	16.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	90.00	1,440.00	
Fluorescein Angiography	4.00	300.00	300.00					300.00				300.00							1,200.00	
Fundus Photography	4.00	115.00	115.00					115.00				115.00							460.00	
SD-OCT	16.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	110.00	1,760.00	
Ocular Blood Flow by Repetitive IOP	28.00	88.00	88.00	176.00		176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	176.00	2,464.00	
Indirect Ophthalmoscopy	28.00	90.00	90.00	180.00		180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	180.00	2,520.00	
Slit Lamp	15.00	100.00	100.00	100.00		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	1,500.00	
Venipuncture/Sample Handling	12.00	20.00	20.00	20.00		20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00					240.00	
Urinalysis	5.00	30.00	30.00					30.00				30.00			30.00				150.00	
Adverse Events Assessment	16.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	800.00	
Per Patient Procedure:			1,518.00	1,186.00	285.00	1,186.00	1,186.00	1,756.00	1,186.00	1,186.00	1,216.00	1,601.00	1,186.00	1,216.00	1,166.00	1,166.00	1,166.00	1,333.00	19,539.00	
Overhead at 30.00%			455.40	355.80	85.50	355.80	355.80	526.80	355.80	355.80	364.80	480.30	355.80	364.80	349.80	349.80	349.80	399.90	5,861.70	
Per Patient Procedure Subtotal:			1,973.40	1,541.80	370.50	1,541.80	1,541.80	2,282.80	1,541.80	1,541.80	1,580.80	2,081.30	1,541.80	1,580.80	1,515.80	1,515.80	1,515.80	1,732.90	25,400.70	

Other Direct Costs	Total	Selected Cost	Visit 1 - Screening	Visit 2 - Day 1	Visit 3 - Week 1	Visit 4 - Week 4	Visit 5 - Week 8	Visit 6 - Week 12	Visit 7 - Week 16	Visit 8 - Week 20	Visit 9 - Week 24	Visit 10 - Week 28	Visit 11 - Week 32	Visit 12 - Week 36	Visit 13 - Week 40	Visit 14 - Week 44	Visit 15 - Week 48	Visit 16 - Week 52 (End of Study)	Total
Physician's Fees without Exam Costs	16.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	2,080.00
Salaries: Coord, Nurse, Admin, Tech	16.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	2,640.00
Pharmacy Dispensing	13.00	20.00		20.00		20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	260.00
Patient Daily Reimbursement	16.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	800.00
Per Patient Other Direct Cost:			345.00	365.00	345.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	365.00	345.00	5,780.00
Overhead at 30.00%			103.50	109.50	103.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	109.50	103.50	1,734.00
Per Patient Other Direct Cost Totals:			448.50	474.50	448.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	474.50	448.50	7,514.00

Cost Per Patient Totals:	2,421.90	2,016.30	819.00	2,016.30	2,016.30	2,757.30	2,016.30	2,016.30	2,016.30	2,055.30	2,555.80	2,016.30	2,055.30	1,990.30	1,990.30	1,990.30	2,181.40	32,914.70
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Invoice Items

Name	Total	Selected Cost	Total
Archiving/Document storage/per site	1.00	650.00	650.00
Closeout Fee	1.00	1,000.00	1,000.00
Initial IRB Fee	1.00	5,000.00	5,000.00
IRB Renewal	Each Year	750.00	
IRB Amendment	1.00	750.00	750.00
Site Start-up Costs	1.00	5,000.00	5,000.00
Initial Pharmacy Fee	1.00	3,900.00	3,900.00
Annual Pharmacy Fee	Each Year	910.00	
SAE report prep fee	Each Year	75.00	
Screen Failure	Each	2,421.90	
Serum Pregnancy Test, Quantitative	2.00	39.00	78.00
Urine Pregnancy Test, Qualitative	13.00	20.00	260.00

Process for building a budget

Industry Sponsored Budget Components

- Personnel Costs
- Procedures
- Labs
- Pharmacy Fees
- Subject Stipends
- Overhead

Process for building a budget

Personnel Costs

- Study Personnel – need “effort” estimates by time (mins/hrs/per visit) and typical personnel and their estimated salary/benefits (MD Investigator, clinical study coordinator (RN), non RN trial coordinator, ...) for each item on the Schedule of Events (SOE)
- Effort must include salary and fringe benefits
- UIC FY19 Fringe Benefit Rate: 35.15%

Process for building a budget

Procedures

Labs

Obtain research rates for each clinical procedure

- Laboratory fees
 - Lab panels vs. individual tests
- Central labs vs local labs
- Overnight shipping
- Radiology
- Clinical supplies
- Pharmacokinetics
 - Serial collections
- Tumor Tissue Collection
 - Fresh Tissue vs. Archival Tissue

Process for building a budget

Pharmacy Fees

Study Drug and Administration

- Infusion vs. IV push vs. Subcutaneous Injection vs. Oral
- Provided by Sponsor vs. Commercially Available
- Dispensing and storage charges

Contact the Investigational Drug Service at UI Health

Process for building a budget

Subject Stipends

- Meals
- Transportation
 - Site Provided or Mileage Reimbursement
 - Parking Stickers
- Sponsor may pay study subject directly

Process for building a budget

Don't Forget to Consider. . .

- Study Start-Up
 - Staff Training
 - Recruitment Activities
- Staff Time
 - Review of Serious Unexpected Serious Events (SUSAR)
 - Investigational New Drug (IND) Reports
 - Remote Monitoring
 - Upload Documents
 - Archive document storage fee \$ rate /year for 7 years
 - Source document binders per subject

Process for building a budget

Don't Forget to Consider. . .

- IRB Review
- IRB Continuing Review Fee
- IRB Amendment Review
- IRB Preparation Fee

Process for building a budget

Overhead on Industry Sponsored Clinical Trials

Indirect Cost Rate (IDC) for Industry Sponsored Studies

The UIC indirect cost rate of 25% TDC (Total Direct Cost Base) applies to ALL procedural and non-procedural line items, as well as, to items that must be invoiced

Process for building a budget

Budgeting for Federally Funded Clinical Trials

- Effort covers all PI's work, including professional fees for clinical services and procedures
- Clinical procedures are to be priced at the research rate for Governmentally-funded research (obtain from UI Health Research Administration)
- General administrative expenses should not be included as direct costs on the budget
- Use current applicable fringe benefit rate (35.15%) and F&A rate (59.9% MTDC)

Process for building a budget

NEGOTIATE NEGOTIATE NEGOTIATE

- Prepare in advance
- Negotiate
- Be prepared to walk away

Why is all of this important?

As a non-profit institution, UIC must recover the full cost of research conducted for outside sponsors, including all associated operating costs (overhead). To do otherwise would result in subsidizing for-profit research and could jeopardize the institution's non-profit status.

Clinical Trials at UIC

For Externally Sponsored Clinical Trials (Industry sponsored/Federally funded/Private Foundation funded)

- Coverage Analysis
- Clinic/Hospital Request for Services Form
- IRB Application
- ORS contract review
- Clinic/Hospital Research Services Billing - study participants need to be placed on the research bill hold

Clinical Trials at UIC

For Principal Investigator (PI) Sponsored Clinical Trials or Department Funded Clinical Trials (no external funding or third-party sponsor)

- Coverage Analysis
- Clinic/Hospital Request for Services Form
- IRB Application
- Clinic/Hospital Research Services Billing - study participants need to be placed on the research bill hold

UIC QUESTIONS

UIC Clinical Trials Website: <http://research.uic.edu/ct>

- Coverage Analysis: covanlysis@uic.edu
- Clinic/Hospital request for services: scottken@uic.edu
- Clinic/Hospital budget review: scottken@uic.edu
- Clinic/Hospital research services billing: scottken@uic.edu
- Contract Review: awards@ic.edu

Questions/Discussion



Next Meeting

Wednesday, November 28th from 1-2pm

Topic:
Subawards and
Sub-recipient monitoring