Planning & Budgeting for Clinical Trials

MUSC
Medical University of South Carolina

Changing What's Possible | MUSC.edu

Learning Objectives

After completion of this course, the learner will be able to:

- Identify key components of a clinical research budget
- Increase your confidence level in supporting the budget negotiation process with a corporate clinical research sponsor

MUSC Clinical Research Liaisons

The Office of Clinical Research welcomes any feedback or suggestions from our clinical research collaborators.

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Contract Research Organization (CRO) Strategic Partnerships

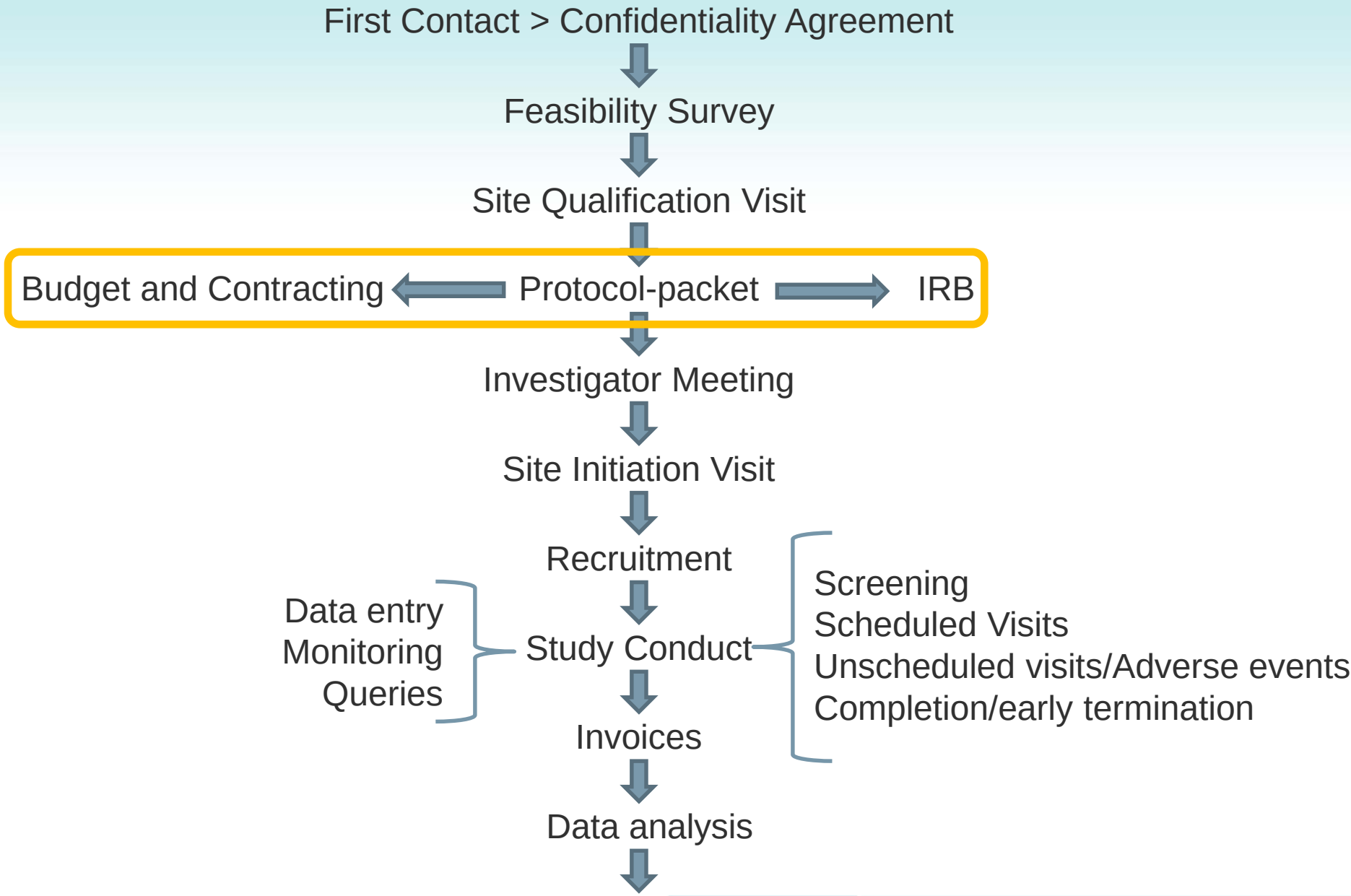
IQVIA™

PPD®

ICON

PAREXEL®
YOUR JOURNEY. OUR MISSION.™

Budgeting Process


First Contact > Confidentiality Agreement
Feasibility Survey
Site Qualification Visit
Budget and Contracting
Protocol-packet
IRB
Investigator Meeting
Site Initiation Visit
Recruitment
Data entry
Monitoring
Queries
Study Conduct
Screening
Scheduled Visits
Unscheduled visits/Adverse events
Completion/early termination
Invoices
Data analysis
Repo
ublication

How many patients do we have?

- How many will qualify considering protocol inclusion/exclusion?
  - Self-service patient count tools (Epic SlicerDicer, MUSC i2b2)
  - Patient registries (Hollings, other)
- How many patients will you need to approach?
- Anticipated screen failure rate?
- Anticipated drop out rate?

How many patients is the sponsor expecting?

- What will be in the contract/informed consent?
- Is the target realistic?
- Poor enrollment = bad value for the sponsor
- It is better to meet your contracted number and request to amend the contract than to over promise and under deliver!

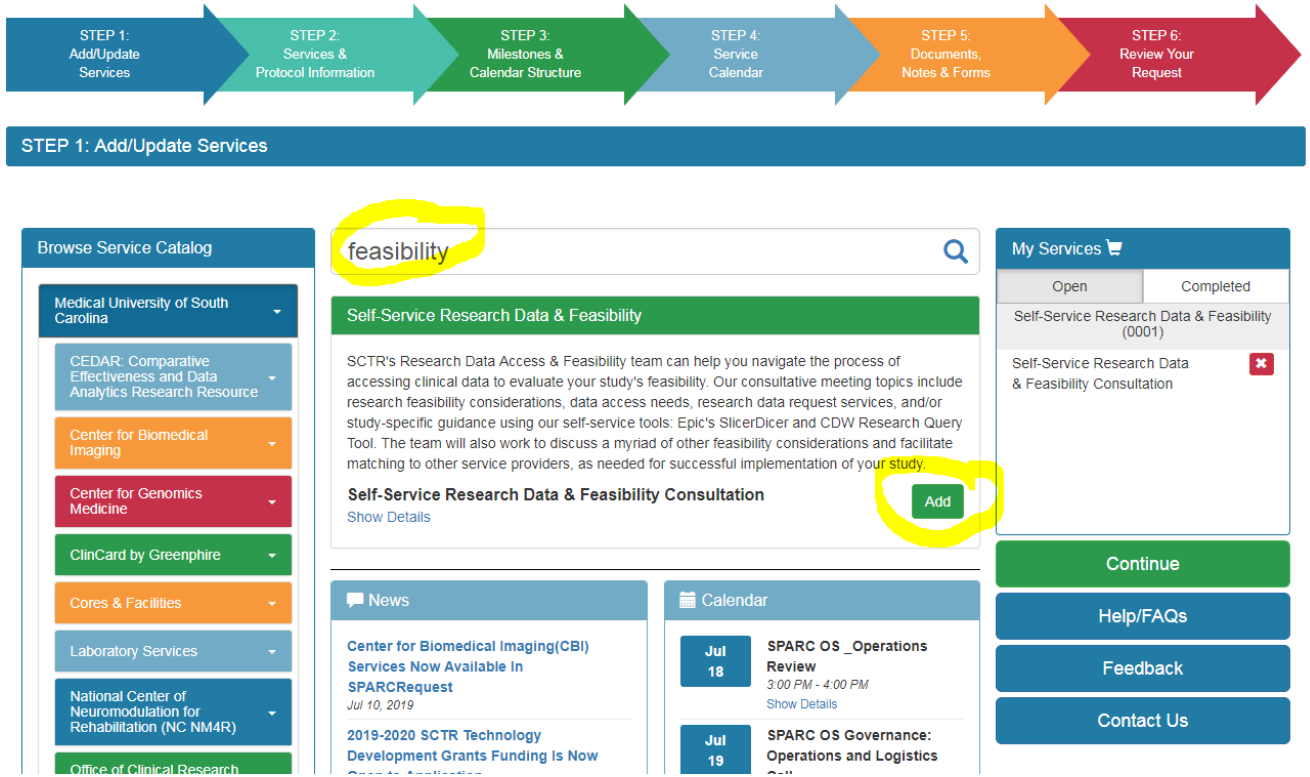
Self-Service Query Tools

Self-Service Research Data & Feasibility Consultation Service

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

SPARCRequest Research Made Easy

MUSC Medical University of South Carolina



- Who will perform protocol related procedures, research coordination, recruitment, regulatory, store/dispense investigational product?
  - What are the personnel requirements?
  - Do we have them on staff? (i.e. Study coordinators, program assistants, etc.)
- What additional services/approvals/equipment/training may be required?

- When will the study begin and end?
  - Add additional time to the sponsor's estimate as recruitment and study duration is often longer than projected
- Where will the study be conducted, do we have the space?
- Which IRB will be utilized (local vs. central)?
- How will you reach the study's recruitment goals?
  - Clinic roster
  - Advertising
  - Epic recruitment report, BPA, etc.

Research Coordination & Management

The SCTR Research Nexus provides a wide range of research coordination and management services for MUSC investigators. The research coordinator staff includes experienced, trained, and VA-credentialed personnel, as well as licensed nurse coordinators. For investigators seeking assistance with management of multi-site trials or day-to-day oversight of research programs, project management services are available.

Services

- Study management and coordination
- Project management
- Regulatory management
- Budget development
- Data management
- Recruitment
- Invoicing and billing
- Quality assurance reviews
- Study assessments (semi-structured interviews, psychometric testing)
- Social-behavioral interventions
- Study record and drug storage for active studies
- Inpatient, outpatient, and outlying clinics, Ralph H. Johnson Veterans Administration
- Support for MUSC researchers for full, partial, or VA-funded studies

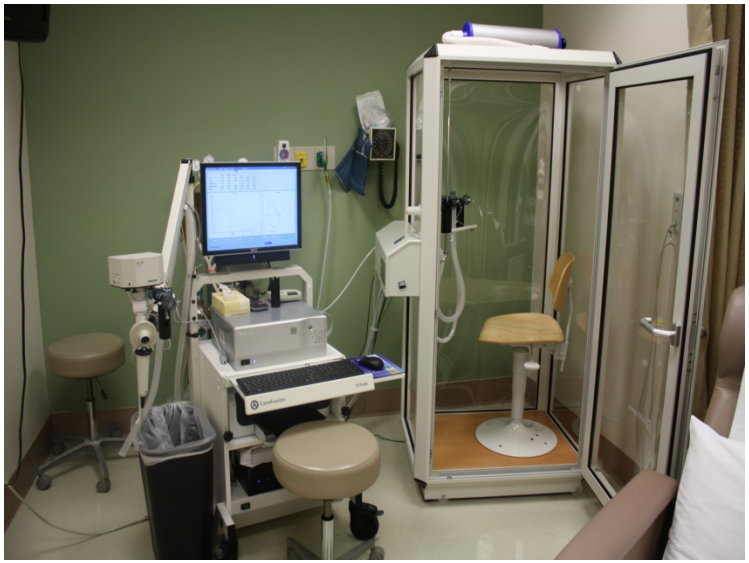
SCresearch.org

SCTR Research Nexus

Phase 1-4 Research Center & Hospital Provider Based Clinic

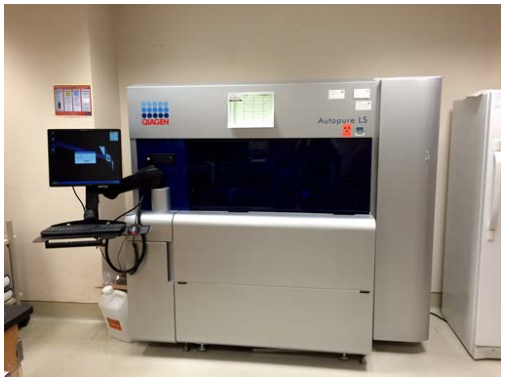
Outpatient, Inpatient & Mobile Nursing
Chemotherapy & Biotherapy Certified Nurses
Nutritionist

6 Examination Rooms
6 Procedure Rooms
1 Infusion Suite



Pulmonary Function Testing Suite

SCTR Research Nexus Laboratory



Qiagen Autopure for Large Volume Automated DNA Extraction

Laminar Flow Hood for PBMC Processing and Aseptic Methods

Fume Hood for Hazardous Chemical Handling and Stool Preps

Six -80°C Freezers, One -20°C Freezer and Two 2-8°C Refrigerators

Investigational Drug Services (IDS)

- Monday through Friday, 8AM to 4:30PM
- 6 staff
- Utilization required for inpatient studies
- All refrigerators and freezers are hooked up to back-up power and alarmed
- Temperatures are monitored remotely
  - 24 hours a day, 7 days a week
  - CheckPoint monitoring system

Who will pay for protocol procedures?

Clinical Trials National Coverage Decision (NCD)

- Intended to extend coverage for routine clinical costs for certain qualifying clinical trials
- Prior to this directive Medicare did not pay for any costs associated with the care of patients enrolled in a clinical trial
- Encourage the participation of older Americans in clinical trials (esp. cancer)

Routine Costs

- Items and services considered conventional care
- Can include items and services for prevention, diagnosis, or treatment of complications associated with the clinical trial

Routine Care vs. Research Costs

- Routine Care are services that would be provided to the patient regardless of study participation (billable to insurance)
- Non-covered services/non-routine services are procedures completed strictly for research purposes (billed to sponsor)

Routine Care vs. Standard of Care

- Routine Care or Conventional Care are services that are covered by Medicare
- Standard of Care may include services not covered by Medicare

"Physician practices should remember that 'necessary' does not always constitute 'covered'…."

OIG Compliance Program Guidance for Individual and Small Group Physician Practices (October 5, 2000)

Risks Associated with Research Billing Non-Compliance

Institutional clinical research billing risks:

1. Billing for services already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial

Clinical Research Billing Principles

Medicare requires a three-part process for clinical research services coverage:

1. Does the study "qualify" for coverage?
2. What items and services are "routine costs"?
3. Do Medicare rules allow coverage of specific "routine costs" within a clinical trial?

MUSC Office of Clinical Research (OCR)

Prospective Reimbursement Analysis (PRA) Process

- Informs the budgeting process
- Sets up research billing calendar
- Used for monitoring & auditing clinical research billing compliance
- Tool to evaluate financial status of a study

Each MUSC Department has assigned a liaison as the primary point of contact with the OCR for Prospective Reimbursement Analysis (PRA) Process

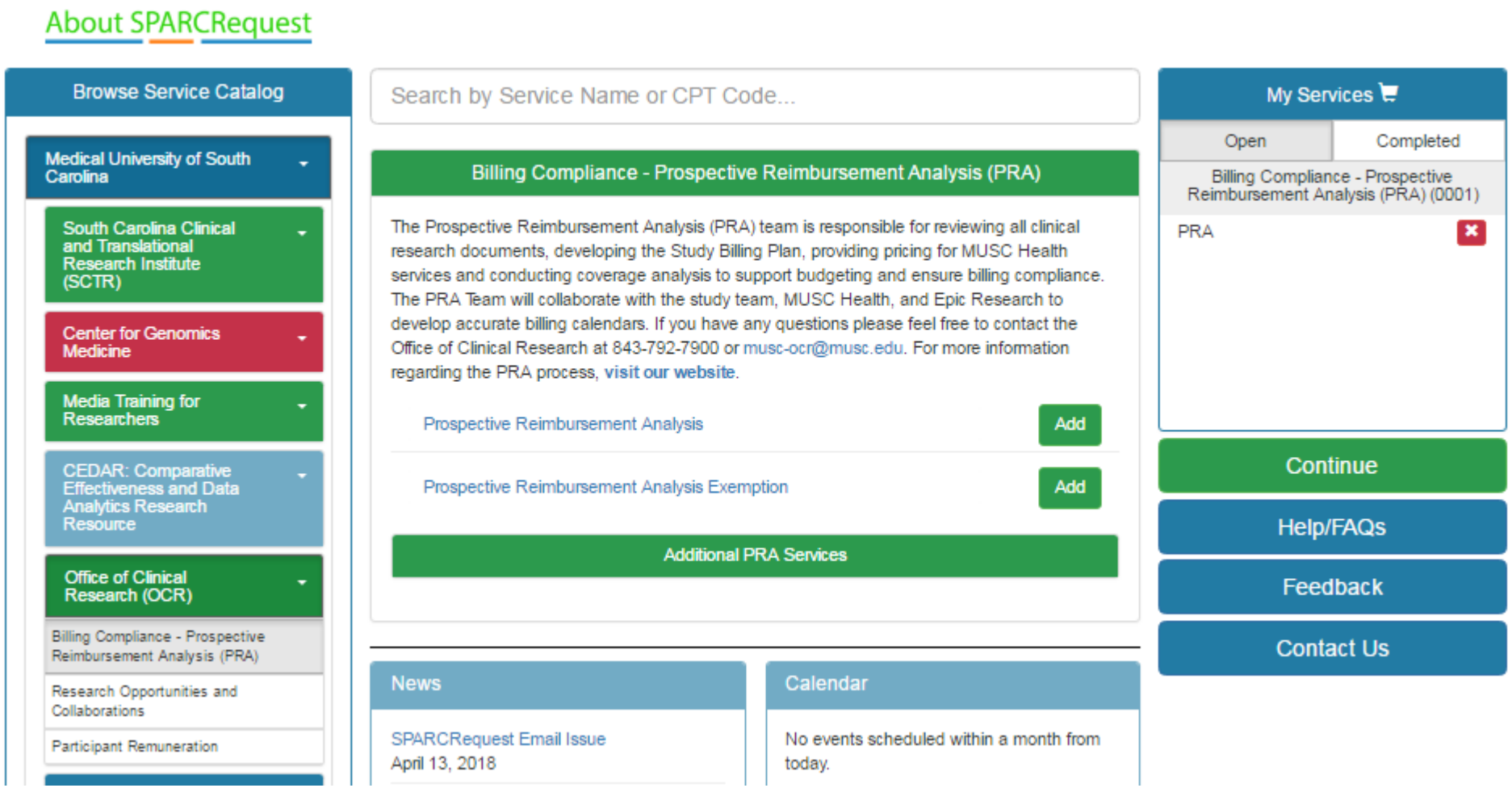
All studies with the potential to include MUSC Health billable services will require a Prospective Reimbursement Analysis by the Office of Clinical Research

- OCR PRA team will partner with study teams to:
  - Map out research workflow
  - Provide feasibility analysis support
  - Build research billing calendar
  - Inform pricing for CPT coded services in study budgets
  - Ensure billing compliance harmonization of documents
- Oncology trials will be included after initial May 1st phase-in

OCR PRA Service will be requested in SPARCRequest®

Regulatory and start up packet, essential documents required

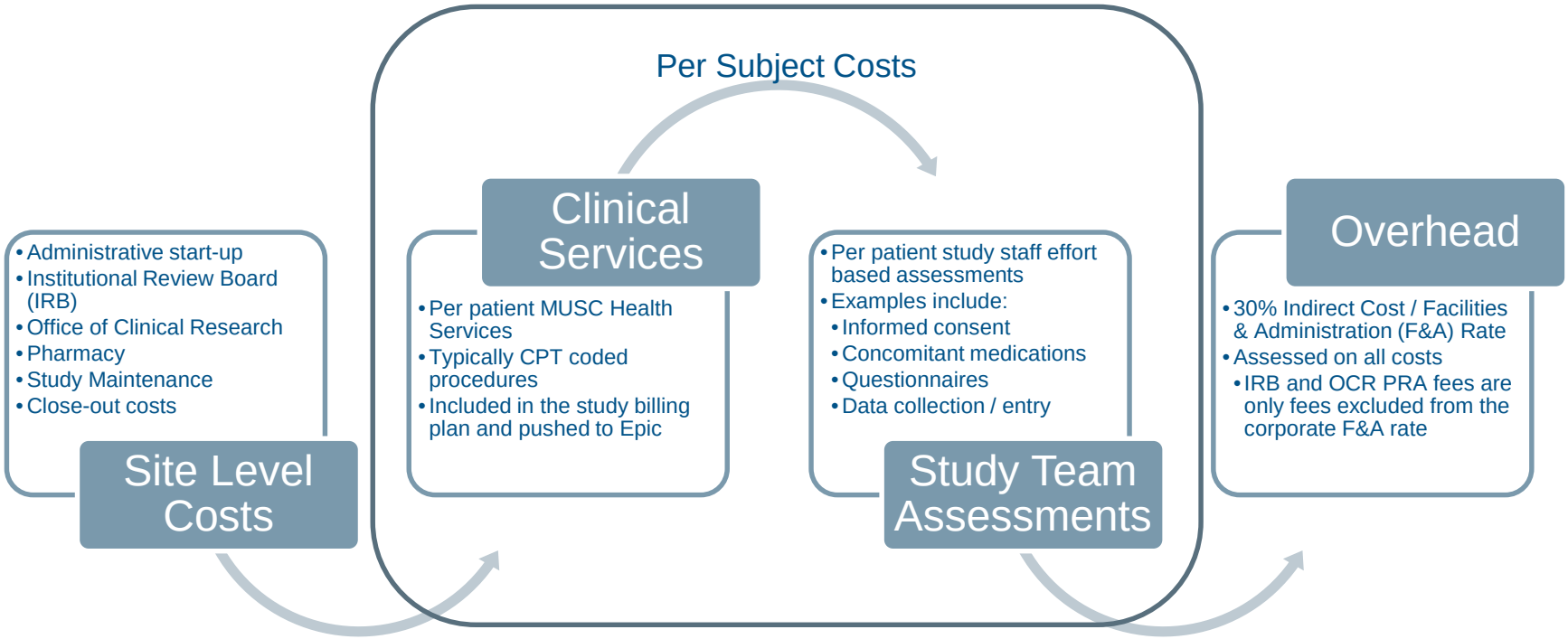
Prospective Reimbursement Analysis Service Request



Budget Categories

- Site level costs
- Per subject costs
- Personnel costs
- Overhead (F&A)

Sponsor Budget Categories

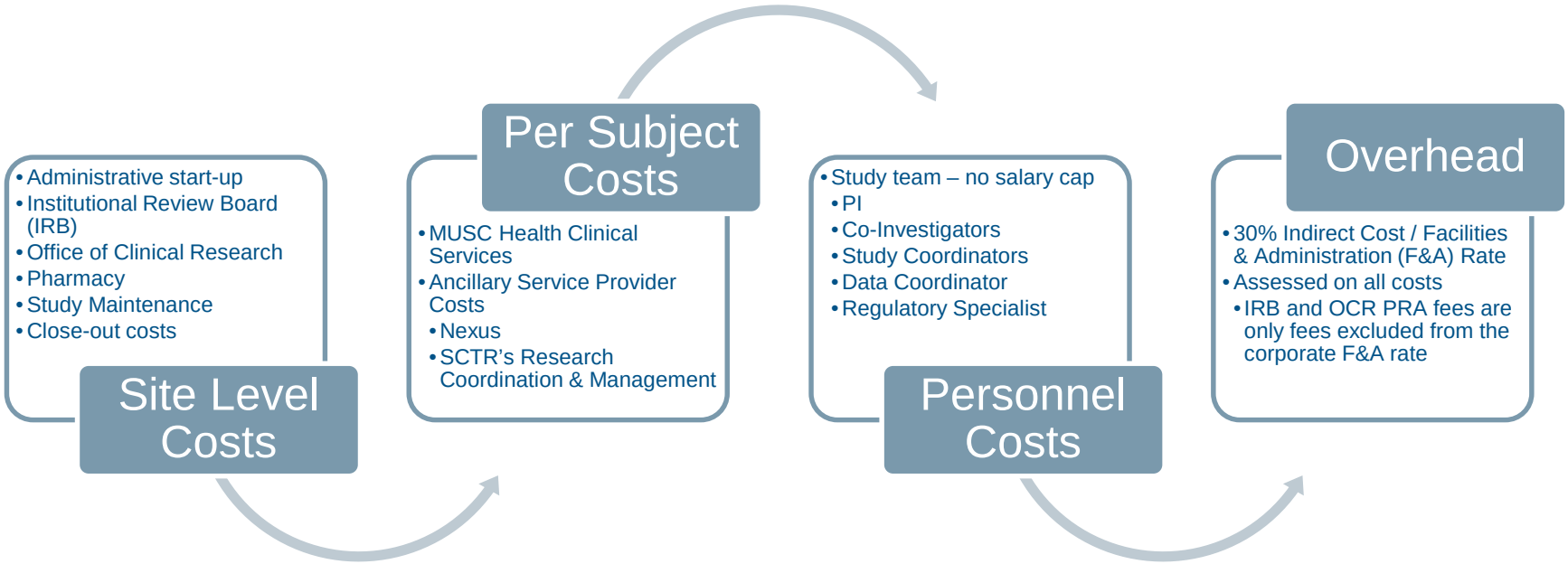


Sponsor Proposal

Procedure	Pre-Op	Operative	6 Months	1 Year	2 Years	5 Years	7 Years	10 Years
Informed Consent	$78							
Inclusion/Exclusion Criteria	$44							
Medical History/Demographics	$40							
Operative (Surgical) procedure/device		$48						
PROMIS Global Health	$17		$17	$17	$17	$17	$17	$17
Ankle Osteoarthritis Score (AOS)	$24		$24	$24	$24	$24	$24	$24
FAOS Questionnaire	$18		$18	$18	$18	$18	$18	$18
TAR Satisfaction			$15	$15	$15	$15	$15	$15
Radiographic Assessment (Investigator requirement) 1	$119		$119	$119	$119	$119	$119	$119
Adverse Event Assessment		$25	$25	$25	$25	$25	$25	$25
Primary Investigator Fee	$60	$60	$60	$60	$60	$60	$60	$60
Study Coordinator Fee	$48	$48	$48	$48	$48	$48	$48	$48
Data Entry	$43	$43	$43	$43	$43	$43	$43	$43
One Subject								**$2,929**

Site Start-Up Fee:	$3,000
IRB Fee	$1,500
IRB Renewal Fee (per year):	$500
Protocol Amendment (per amendment):	$500
Archiving Fee At Study Close:	$500
Site Monitoring Fee (per visit):	$384
Site Close-Out Fee:	$500
Serious Adverse Event (per event):	$100
X-Rays (Outside standard of care):	$76
Unscheduled visits as described in the protocol and will be paid based on CRF deliverable as provided in the fee schedule above	

Internal Budget Categories



Site Level Costs – Start-up

These are the charges for activities spent getting a study up and running

If there is no budget agreement & contract, you will not be paid

Most of the budget captures time spent

- Protocol review
- Preparing a budget
- Regulatory submission (IRB forms)
- Pharmacy review and setup

Site Level Costs – Other

In addition to startup there are other site level costs. Study maintenance costs, such as:

- Freezer storage
- Record storage
- Monitor change fee
- Close out costs
- Etc.

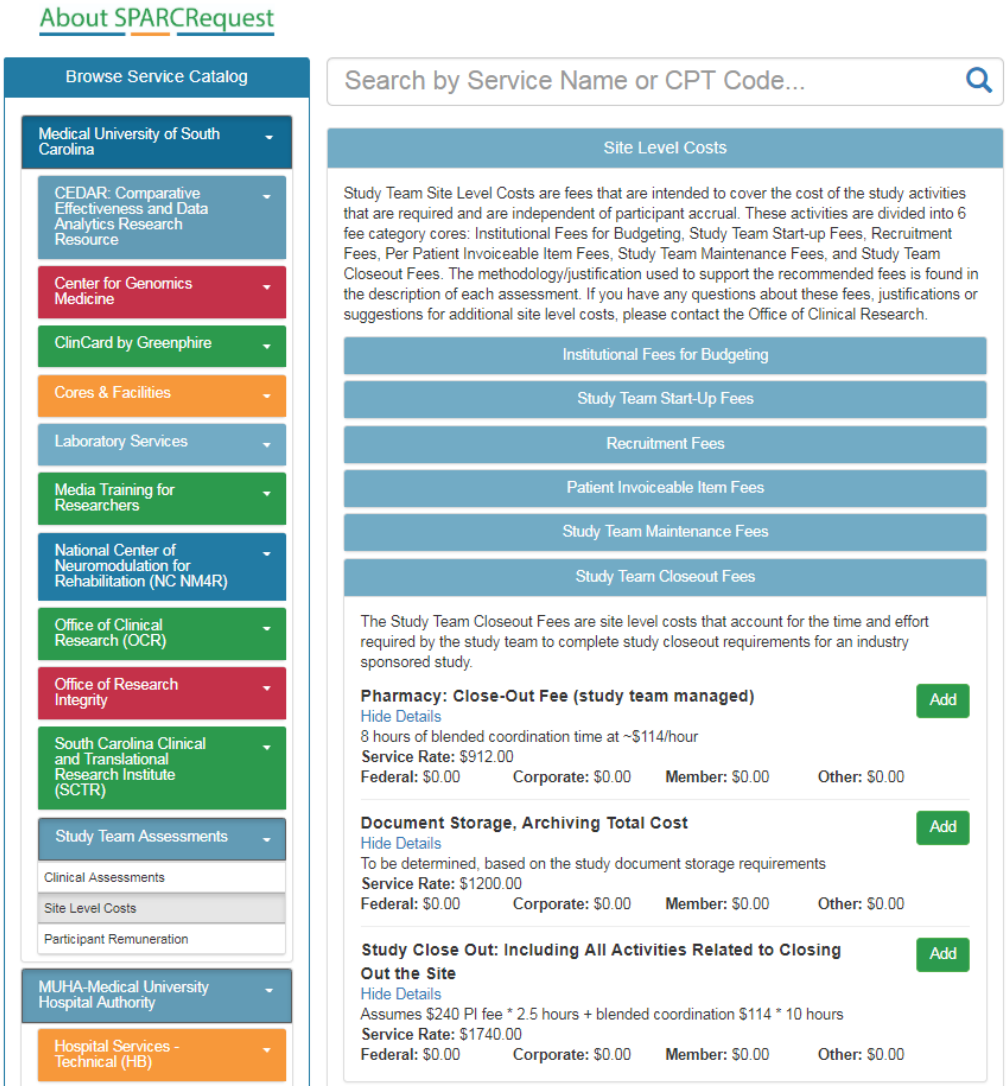
These are often listed itemized as invoiceable costs

Site Level Costs

These are the charges for activities spent getting a study up and running and study maintenance

- Start-up
- Service provider fees
  - Institutional Review Board (IRB) fees
  - Prospective Reimbursement Analysis (PRA) fees
  - Investigational Drug Services (IDS) fees
  - Radiology Review fees
- Per patient invoiceable items
- Study maintenance costs
- Close out costs

For more justification information, visit the Office of Clinical Research on the horseshoe here



Site Level Costs – First Round

Other Services	Service Rate	Sponsor Unit Cost (Negotiated Reimbursement)	Research Cost (Your Cost)	Procedure Occurence (N)	F&A Applies?	Total Cost to Sponsor (+OH)	Margin to Cover Personnel Effort
Study Level Services (Pass Through)							
Prospective Reimbursement Analysis (0002)	$ 2,000.00	$ 2,000.00	$ 2,000.00	1	N	$ 2,000.00	$ -
Prospective Reimbursement Analysis Amendment Fee	$ 500.00	$ 500.00	$ 500.00	1	N	$ 500.00	$ -
Study Start-Up Fee/Site Set-Up Fee (0005)	$ 9,540.00	$ 9,540.00	$ -	1	Y	$ 12,402.00	$ 9,540.00
Annual Study Maintenance Fee (billing compliance, sponsor/CRO correspondence, ongoing patient	$ 5,544.00	$ 5,544.00	$ -	11	Y	$ 79,279.20	$ 60,984.00
Daily Monitoring Visit Fee (0005)	$ 804.00	$ 804.00	$ -	12	Y	$ 12,542.40	$ 9,648.00
IRB Document Study Team Preparation Fee for Amendments, Continuing Reviews, Termination (0	$ 582.00	$ 582.00	$ -	1	Y	$ 756.60	$ 582.00
Site Audit, Quality Audit, Clinical Trial Master File Audit (0005)	$ 2,118.00	$ 2,118.00	$ -	1	Y	$ 2,753.40	$ 2,118.00
Document Storage, Archiving Total Cost (0005)	$ 1,200.00	$ 1,200.00	$ -	1	Y	$ 1,560.00	$ 1,200.00
Study Close Out: Including All Activities Related to Closing Out the Site (0005)	$ 1,740.00	$ 1,740.00	$ -	1	Y	$ 2,262.00	$ 1,740.00
Initial Protocol Review (0006)	$ 2,500.00	$ 2,500.00	$ 2,500.00	1	N	$ 2,500.00	$ -
Continuing Review (0006)	$ 750.00	$ 750.00	$ 750.00	11	N	$ 8,250.00	$ -
IRB Amendment (0006)	$ 500.00	$ 500.00	$ 500.00	1	N	$ 500.00	$ -
Imaging Protocol Review (Level 1) (0009)	$ 300.00	$ 300.00	$ 300.00	1	Y	$ 390.00	$ -
Serious adverse events (SAE)	$ 348.00	$ 348.00	$ -	1	Y	$ 452.40	$ 348.00
Study Level Services: Total Cost						**$ 126,148.00**	**$ 86,160.00**

Site Level Costs – Final

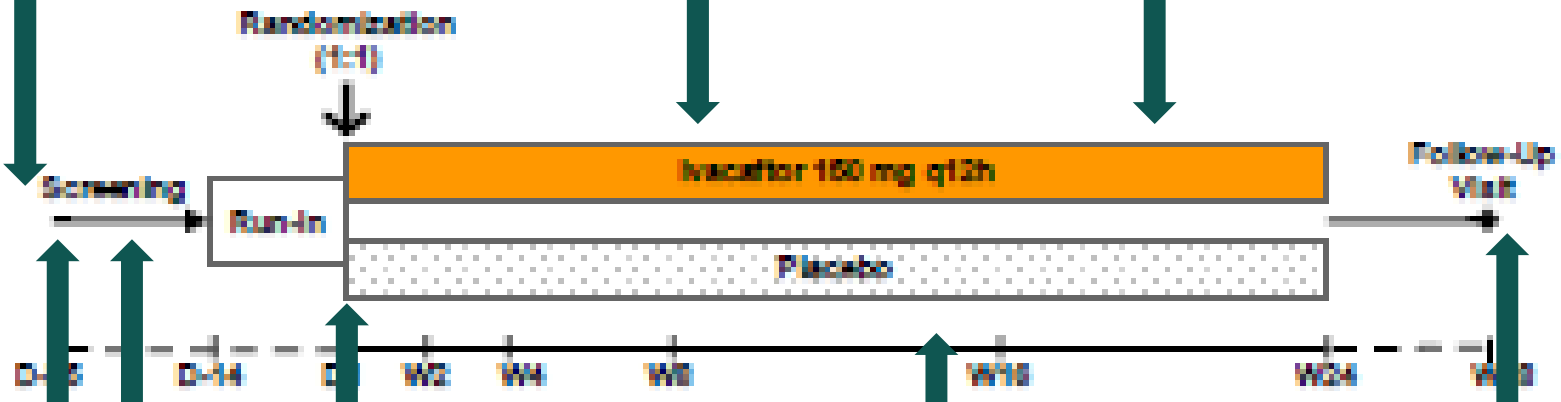
Other Services	Service Rate	Sponsor Unit Cost (Negotiated Reimbursement)	Research Cost (Your Cost)	Procedure Occurence (N)	F&A Applies ?	Total Cost to Sponsor (+OH)	Margin to Cover Personnel Effort
Study Level Services (Pass Through)							
~~Prospective Reimbursement Analysis (0002)~~ - fee not accepted by sponsor	$ 2,000.00	$ -	$ 2,000.00	1	N	$ -	$ - 2,000.00
Clinical Research Fee - will cover most of the OCR PRA fee	$ -	$ 1,528.00	$ -	1	N	$ 1,528.00	$ 1,528.00
Study Start-Up Fee/Site Set-Up Fee (0005)	$ 9,540.00	$ 3,860.00	$ -	1	Y	$ 5,018.00	$ 3,860.00
Administrative Fee (billing compliance, sponsor/CRO correspondence, ongoing patient screening/r	$ 5,544.00	$ 2,000.00	$ -	1	Y	$ 2,600.00	$ 2,000.00
Daily Monitoring Visit Fee (0005)	$ 804.00	$ 804.00	$ -	12	Y	$ 12,542.40	$ 9,648.00
IRB Document Study Team Preparation Fee for Amendments, Continuing Reviews, Termination (0	$ 582.00	$ 580.00	$ -	12	Y	$ 9,048.00	$ 6,960.00
Site Audit, Quality Audit, Clinical Trial Master File Audit (0005)	$ 2,118.00	$ 1,650.00	$ -	1	Y	$ 2,145.00	$ 1,650.00
Document Storage, Archiving Total Cost (0005)	$ 1,200.00	$ 771.50	$ -	1	Y	$ 1,002.95	$ 771.50
Study Close Out: Including All Activities Related to Closing Out the Site (0005)	$ 1,740.00	$ 1,100.00	$ -	1	Y	$ 1,430.00	$ 1,100.00
Initial Protocol Review (0006)	$ 2,500.00	$ 2,500.00	$ 2,500.00	1	N	$ 2,500.00	$ -
Continuing Review (0006)	$ 750.00	$ 750.00	$ 750.00	11	N	$ 8,250.00	$ -
IRB Amendment (0006)	$ 500.00	$ 500.00	$ 500.00	1	N	$ 500.00	$ -
Imaging Protocol Review (Level 1) $428 of this fee will go to OCR PRA	$ 300.00	$ 629.00	$ 300.00	1	Y	$ 817.70	$ 329.00
Obtain copies of diagnostic films, X-rays	$ 76.00	$ 76.00	$ -	1	Y	$ 98.80	$ 76.00
Serious adverse events (SAE)	$ 348.00	$ 200.00	$ -	1	Y	$ 260.00	$ 200.00
Study Level Services: Total Cost						**$ 47,740.85**	**$ 26,122.50**

Per subject costs

Recruitment Pre-screening

Scheduled visits

Results



Consenting

Screening

Pharmacy

Processing/shipping

Closure/payment

Per Subject Costs: Events During Study

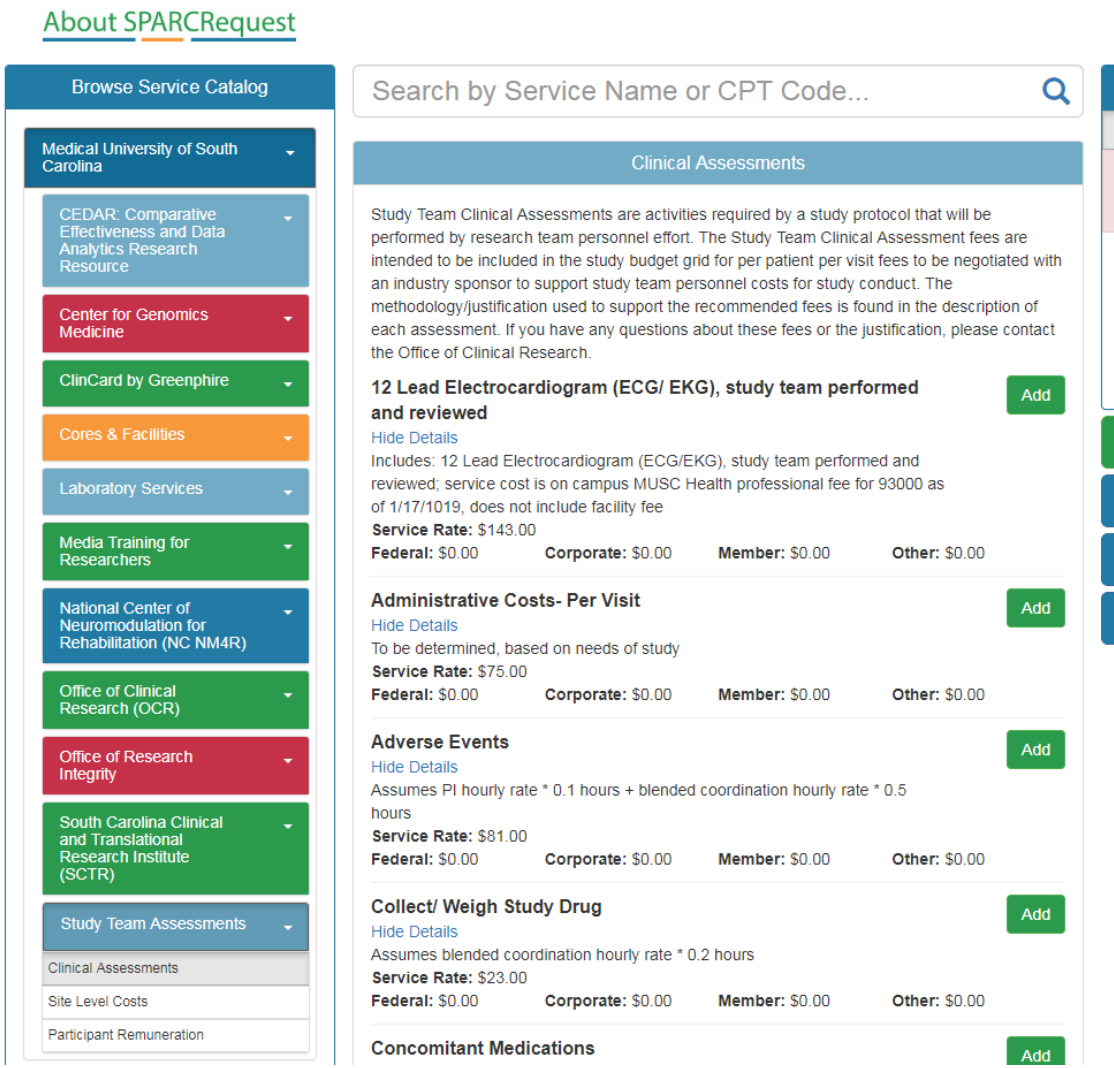
SCHEDULE of EVENTS

Procedures	Pre-op	Op.	6 mo +/-30 days	1 yr +/-60 days	2 yr +/-60 days	5 yr +/-60 days	7 yr +/-60 days	10 yr +/-60 days	Study Close
Informed Consent	X								
Inclusion/Exclusion Criteria	X								
Medical History/Demographics	X								
Operative (Surgical) procedure/device		X							
PROMIS Global Health	X		X	X	X	X	X	X	
Ankle Osteoarthritis Score (AOS)	X		X	X	X	X	X	X	
FAOS Questionnaire	X		X	X	X	X	X	X	
Total Ankle Replacement Satisfaction			X	X	X	X	X	X	
Radiographic Assessment (Investigator requirement)	X		X	X	X	X	X	X	
Adverse Event Assessment			X	X	X	X	X	X	
End of Study									X
Surgical Intervention[1]									
*Sponsor-approved Unscheduled Visit [2]									

[1]&[2] These are not scheduled time point events but will be observed for throughout study participation.

Per Subject Costs

- CPT Coded Procedures: work with OCR PRA team
- Informed Consent
- Retention activities
- Weight / vital signs
- Demographics
- Questionnaires
- Patient remuneration + fees
- Adverse event reporting (AE)
- Blood draws
- Labs, PK samples
- Shipping Samples



Per Patient Costs – 1st Round

Selected Services	CPT Code	Service Rate	Sponsor Unit Cost (Negotiated Reimbursement)	Research Cost (Your Cost)	# of Subjects	Pre-op		Operative		6 month		1 Year		2 Year		5 Year		7 Year		10 Year		Total Sponsor Unit Cost Per Patient	Total Research Cost Per Patient
ITAR						-14		0		180		365		730		1825		2555		3650			
						R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T		
Study Team Assessments(0005)																							
Informed Consent		$ 174.00	$ 174.00	$ -	20	1																$ 174.00	$ -
Inclusion/Exclusion Criteria		$ 117.00	$ 117.00	$ -	20	1																$ 117.00	$ -
Medical History with Demographics		$ 117.00	$ 117.00	$ -	20	1																$ 117.00	$ -
Operative (Surgical) Data Collection		$ 57.00	$ 57.00	$ -	20			1														$ 57.00	$ -
Quality of Life Questionnaire, General (QOL)		$ 46.00	$ 46.00	$ -	20	1				1		1		1		1		1		1		$ 322.00	$ -
Osteoarthritis Pain Intensity Visual Analog Scale		$ 30.00	$ 30.00	$ -	20	1				1		1		1		1		1		1		$ 210.00	$ -
Orthopaedic Outcome Score Questionnaire		$ 46.00	$ 46.00	$ -	20	1				1		1		1		1		1		1		$ 322.00	$ -
Device/Medication Satisfaction Assessment		$ 29.00	$ 29.00	$ -	20					1		1		1		1		1		1		$ 174.00	$ -
Investigator Radiographic Assessment Data Collection		$ 120.00	$ 120.00	$ -	20	1				1		1		1		1		1		1		$ 840.00	$ -
Adverse Events		$ 81.00	$ 81.00	$ -	20			1		1		1		1		1		1		1		$ 567.00	$ -
Physician-Per Hour		$ 240.00	$ 240.00	$ -	20	1		1		1		1		1		1		1		1		$ 1,920.00	$ -
Study Coordinator-Per Hour		$ 114.00	$ 114.00	$ -	20	1		1		1		1		1		1		1		1		$ 912.00	$ -
Data Entry-Per Hour		$ 58.00	$ 58.00	$ -	20	1		1		1		1		1		1		1		1		$ 464.00	$ -
Research Device (0010)																							
Device		$ -	$ -	$ -	20		1															$ -	$ -
Radiology (PB-Outreach)(0011)																							
CHG X-RAY ANKLE 3+ VW	73610	$ 162.00	$ 162.00	$ 8.62	20		1				1		1		1		1		1		1	$ -	$ -
Total per Patient per Visit (-OH)						$1,062.00		$550.00		$764.00		$764.00		$764.00		$764.00		$764.00		$764.00		$ 6,196.00	
Total Overhead Cost per Visit						$ 318.60		$165.00		$229.20		$229.20		$229.20		$229.20		$229.20		$229.20		$ 1,858.80	
Total per Patient per Visit (+OH)						$1,380.60		$715.00		$993.20		$993.20		$993.20		$993.20		$993.20		$993.20		$ 8,054.80	
Total Margin per Patient per Visit						$1,062.00		$550.00		$764.00		$764.00		$764.00		$764.00		$764.00		$764.00			
Total Margin per Study for per Patient Assessments	**$ 123,920.00**																						
ITAR: Summary																							
ITAR: Total Cost (-OH) per Patient			**$ 6,196.00**																				
ITAR: Total Cost (+OH) per Patient			**$ 8,054.80**																				
ITAR: Total Margin per Patient			**$ 6,196.00**																				
MUSC increase over sponsor initial offer			**175%**																				

Per Patient Costs – Final

Selected Services	CPT Code	Service Rate	Sponsor Unit Cost (Negotiated Reimbursement)	Research Cost (Your Cost)	# of Subjects	Pre-op		Operative		6 month		1 Year		2 Year		5 Year		7 Year		10 Year		Total Sponsor Unit Cost Per Patient	Total Research Cost Per Patient
ITAR						-14		0		180		365		730		1825		2555		3650			
						R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T		
Study Team Assessments(0005)																							
Informed Consent		$ 174.00	$ 125.00	$ -	20	1																$ 125.00	$ -
Inclusion/Exclusion Criteria		$ 117.00	$ 117.00	$ -	20	1																$ 117.00	$ -
Medical History with Demographics		$ 117.00	$ 50.00	$ -	20	1																$ 50.00	$ -
Operative (Surgical) Data Collection		$ 57.00	$ 57.00	$ -	20			1														$ 57.00	$ -
Quality of Life Questionnaire, General (QOL)		$ 46.00	$ 36.00	$ -	20	1				1		1		1		1		1		1		$ 252.00	$ -
Osteoarthritis Pain Intensity Visual Analog Scale		$ 30.00	$ 30.00	$ -	20	1				1		1		1		1		1		1		$ 210.00	$ -
Orthopaedic Outcome Score Questionnaire		$ 46.00	$ 25.00	$ -	20	1				1		1		1		1		1		1		$ 175.00	$ -
Device/Medication Satisfaction Assessment		$ 29.00	$ 29.00	$ -	20					1		1		1		1		1		1		$ 174.00	$ -
Investigator Radiographic Assessment Data Collection		$ 120.00	$ 120.00	$ -	20	1				1		1		1		1		1		1		$ 840.00	$ -
Adverse Events		$ 81.00	$ 28.00	$ -	20			1		1		1		1		1		1		1		$ 196.00	$ -
Physician- (half hour alloted for this study)		$ 240.00	$ 104.50	$ -	20	1		1		1		1		1		1		1		1		$ 836.00	$ -
Study Coordinator		$ 114.00	$ 58.00	$ -	20	1		1		1		1		1		1		1		1		$ 464.00	$ -
Data Entry-Per Hour		$ 58.00	$ 52.00	$ -	20	1		1		1		1		1		1		1		1		$ 416.00	$ -
Research Device (0010)																							
Device		$ -	$ -	$ -	20		1															$ -	$ -
Radiology (PB-Outreach)(0011)																							
CHG X-RAY ANKLE 3+ VW	73610	$ 162.00	$ 162.00	$ 8.62	20		1				1		1		1		1		1		1	$ -	$ -
Total per Patient per Visit (-OH)						$ 717.50		$ 299.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50		$ 3,912.00	
Total Overhead Cost per Visit						$ 215.25		$ 89.85		$ 144.75		$ 144.75		$ 144.75		$ 144.75		$ 144.75		$ 144.75		$ 1,173.60	
Total per Patient per Visit (+OH)						$ 932.75		$ 389.35		$ 627.25		$ 627.25		$ 627.25		$ 627.25		$ 627.25		$ 627.25		$ 5,085.60	
Total Margin per Patient per Visit						$ 717.50		$ 299.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50		$ 482.50			
Total Margin per Study for per Patient Assessments	$ 78,240.00																						
ITAR: Summary																							
ITAR: Total Cost (-OH) per Patient			$ 3,912.00																				
ITAR: Total Cost (+OH) per Patient			$ 5,085.60																				
ITAR: Total Margin per Patient			$ 3,912.00																				
MUSC increase over sponsor initial offer			74%																				

Service Rate versus Your Cost

- For industry funded studies, typically request full price of a service
- Difference between full cost and research rate for services can be applied to effort/personnel costs
- Remaining funds on an industry sponsored study are research contingency/development funds
- Example: ankle X-ray CPT code 73610
  - Service rate $162 = fee sponsor pays site for the service
  - Your cost $8.62 = research bill study will pay
  - Difference $153.38 = personnel costs/contingency funds

Personnel Costs

Study Team

- PI
- Co-Investigators
- Study Nurse
- Study Coordinator(s)
- Data Coordinator
- Program Assistants

Administration

- Billing/Finance Manager
- Regulatory Coordinator

Considerations for estimating time

- Pre-screening: how complicated are the inclusion/exclusion criteria?
- Informed consent
  - Estimate time to answer questions
  - Length of Informed Consent Document
  - Legally Authorized Representative (LAR) will take additional time
- Medical history: How big is the medical record?
- Surveys: Will the patient be able to read the entire survey?
- Drug administration: How complicated is the drug delivery?
- Visit prep and scheduling: Are there additional appointments needed?
- Specimen handling: Review the instructions carefully
- Data entry: Are data entered electronically?
- General considerations: Are you including pediatric patients?

Personnel Costs

Study Information							
SPARC Study ID:							
RMID:							
Short Title:	ITAR						
Protocol Title:	INFINITY Total Ankle Replacement Follow-up (ITAR)						
Sponsor:	ABC Medical Supply						
Primary PI Name:	Minnie Mouse						
Business Manager:	Tinker Bell						
Funding Source:	Industry-Initiated/Industry-Sponsored						
Indirect Cost Rate:	30%						
Staff Fringe Rate:	38.4%						
Authorized Users							
Name	**Role**	**Institutional Base**	**% Effort**	**Project Period (i**	**Salary Requested**	**Fringe**	**Total**
Minnie Mouse	Primary PI	$ 225,000.00	0.5%	144	$ 13,500.00	$ 5,184.00	$ 18,684.00
Donald Duck	Research Assistant/Coordinator	$ 38,000.00	10%	144	$ 45,600.00	$ 17,510.40	$ 63,110.40
Daisy Duck	General Access User	$ -	0%	144	$ -	$ -	$ -
Total					**$ 59,100.00**	**$ 22,694.40**	**$ 81,794.40**

Potential Hidden Costs

Time not accounted for:

- Screening
- Training (including investigator meeting)
- Monitor visits
- Queries
- Serious adverse events

Supplies

- Not all supplies will be provided (e.g. IV)

Breakeven Analysis

Formula assumptions:

- All patients complete all visits
- Study runs within the project period
- No changes to personnel effort allocations

Study Budget		
Total Study Cost (Sponsor Cost)	$	149,452.85
Total Margin	$	104,362.50
Study Contingency	$	22,568.10
Breakeven Analysis		14
Total Budget	$	149,452.85

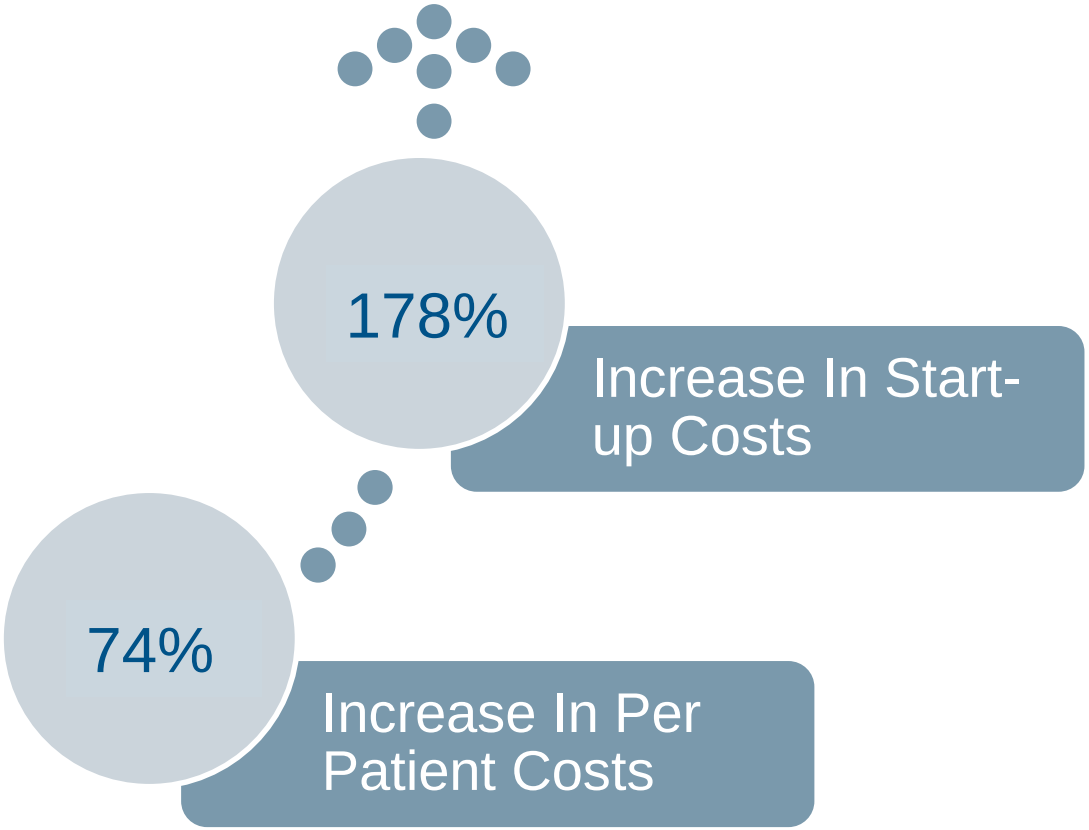
Final Executed Budget in Contract

Procedure	Pre-Op	Operative	6 Months	1 Year	2 Years	5 Years	7 Years	10 Years
Informed Consent	$162.50							
Inclusion/Exclusion Criteria	$152.10							
Medical History/Demographics	$65							
Operative (Surgical) procedure/device		$74.10						
PROMIS Global Health	$46.80		$46.80	$46.80	$46.80	$46.80	$46.80	$46.80
Ankle Osteoarthritis Score (AOS)	$39		$39	$39	$39	$39	$39	$39
FAOS Questionnaire	$32.50		$32.50	$32.50	$32.50	$32.50	$32.50	$32.50
TAR Satisfaction			$37.70	$37.70	$37.70	$37.70	$37.70	$37.70
Radiographic Assessment (Investigator requirement) [1]	$156		$156	$156	$156	$156	$156	$156
Adverse Event Assessment		$36.40	$36.40	$36.40	$36.40	$36.40	$36.40	$36.40
Primary Investigator Fee	$135.85	$135.85	$135.85	$135.85	$135.85	$135.85	$135.85	$135.85
Study Coordinator Fee	$75.40	$75.40	$75.40	$75.40	$75.40	$75.40	$75.40	$75.40
Data Entry	$67.60	$67.60	$67.60	$67.60	$67.60	$67.60	$67.60	$67.60
One Subject								**$5085.60**

All charges below (inclusive of overhead) are study requirements and will be invoiced at the time they occur.

Site Start-Up Fee:	$5,018
Administrative Fee (billing compliance, sponsor/CRO correspondence, ongoing patient screening/retention, training, administrative costs, etc.)	$2,600
Clinical Research Fee	$1572
IRB Fee	$2,500
IRB Renewal Fee (per year):	$750
Protocol Amendment (per amendment):	$500
IRB Document Study Team Preparation Fee for Amendments, Continuing Reviews, Termination	$754
Radiology Set-Up Fee	$818
Archiving Fee At Study Close:	$1,003
Site Monitoring Fee (per visit):	$1,045.20
Site Audit, Quality Audit, Clinical Trial Master File Audit	$1,672
Site Close-Out Fee:	$1,430
Serious Adverse Event (per event):	$260
Obtain copies of diagnostic films, X-Rays	$98.80
Unscheduled visits as described in the protocol and will be paid based on CRF deliverable as provided in the fee schedule above	

Case Study: Budgeting Impact



OCR Finance Website Resources

Log Out | Visit Other MUSC Sites | MyQuest

MUSC Medical University of South Carolina

Office of Clinical Research

Prospective Reimbursement Analysis | Finance | Feasibility | ClinCard | ClinicalTrials.gov

Home > Research > Office of Clinical Research > Finance > Budget Negotiations

Budget Negotiations

Negotiation is the process of reaching a mutual agreement; in this case MUSC and the sponsor are agreeing on the payment terms of a contract or other legal document. During budget negotiations MUSC and the sponsor propose and counter-propose costs to arrive at a mutually agreeable budget. The objective of the negotiation process is to end up with an appropriately funded clinical research study. As you begin negotiating, it is important to be prepared and knowledgeable about the clinical research study. Advanced planning, preparation and patience are key skills in a successful negotiation.

- Internal versus Sponsor Budget: negotiate in sponsor budget format
  - Know your true costs and breakeven
  - Leave room to negotiate/meet in the middle
- Fair Market Value (FMV)
  - Be prepared to justify your costs
  - Justification documentation

Justification Documentation Language Examples to Support the Negotiation Process

Justification Documentation

Version: 1.0 - Date: 10/23/2018

MUSC
Medical University of South Carolina

Office of Clinical Research
Office of the Vice President for Research
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Charleston SC 29425-1750
Tel 843 792 7900
Musc-ocr@musc.edu

Instructions for use:
This document contains example justification documentation to support the budget negotiation process with industry sponsors for corporate clinical research studies.

When your study specific justification documentation is completed, please utilize your research department letterhead and save as a PDF to provide to the sponsor.

Institutional Fees

F&A Rate

An overhead rate of 30% TDC is required by the Institution in order to participate in clinical research studies. This overhead rate is charged to all Pharmaceutical Companies and Device Manufacturers for all Clinical Research Studies. The 30% is charged on all costs excluding IRB fees. The overhead is taken directly from payments received and is not part of the compensation paid to the Principal Investigator.

Standard Holdback Language

The standard acceptable holdback percentage for clinical research payments for industry sponsored clinical research studies in which MUSC participates is ten percent (10%).

MUSC expects that at least ninety percent (90%) of each payment due will be made under the terms of the Clinical Trial Agreement, typically upon verification of visit completion or receipt of invoice and that the balance of monies earned, up to ten percent (10%), will be paid to MUSC under the terms of the Clinical Trial Agreement, typically upon acceptance of the Case Report Forms at the end of the study.

Office of Research Integrity Institutional Board for Human Research (IRB) Fees

The IRB Initial Protocol Review fee of $2500 is charged upon initial submission for IRB review by MUSC.

The IRB Continuing Review fee of $750 is charged annually by MUSC.

What are Hidden Costs?

Time not accounted for:

- Screening
- Training (including investigator meeting)
- Monitor visits
- Queries
- Serious adverse events

Supplies

- Not all supplies will be provided (e.g. IV)

Service Rate versus Your Cost

- For industry funded studies, request full price of a service
- Difference between full cost and research rate for services can be applied to effort/personnel costs
- Any remaining funds on an industry sponsored study budget are study contingency/development funds
- Example: venipuncture CPT code 36415
  - Service rate $26 = sponsor pays
  - Your cost $4.42 = research team pays from study account
  - Difference $21.58 = personnel costs/contingency funds

Internal Budget

- Actual costs/activity
- Contingency Funds
- Project Period
- Personnel effort
- Breakeven analysis
- Indirect cost on (almost) all costs
- Max compensation calculation (ORSP)

VS

Sponsor Budget

- Charges to sponsor
  - Mark up rolled into the charges
- No contingency (viewed as profit by a sponsor)
- Sponsor format
  - Usually in per patient format
- Indirect costs /Overhead

- Internal versus Sponsor Budget: negotiate in sponsor budget format
  - Know your true costs and breakeven
  - Leave room to negotiate/meet in the middle
- Fair Market Value (FMV)
  - Be prepared to justify your costs
  - Justification documentation
- Providing a realistic enrollment number is key
- Review contract language (screen fails, holdback, etc.)

- Route completed budget and CTA document in ePDS for review and approval
- ORSP will review legal terms
- ORSP will notify study team when document is ready for to be signed by PI and then executed by an institutional official within ORSP

What goes in the contract?

- Requirements for study conduct

(c) The Principal Investigator shall be responsible for performing the Study and for the direct supervision of any individual performing any portion of the Study (the "**Study Staff**"). In the event one or more sub-investigators provide services under this Agreement, Institution and Principal Investigator shall ensure that each sub-investigator (i) has the experience, qualifications and capabilities to perform the Study in a timely, professional and competent manner; and (ii) agrees to comply with the terms of this Agreement and the Protocol. The Principal Investigator shall use independent medical judgment in determining the eligibility of a Study subject to participate in the Study and as to all aspects of a Study subject's medical care.

1.2 *Study Treatment*. Vertex shall provide Institution, at no cost, such quantities of the investigational drugs and other drugs as may be required for the Study (collectively, the "**Study Treatment**"). Institution shall safeguard the Study Treatment with the same degree of care used for its own property and in accordance with the Protocol and Applicable Law. Institution shall, following completion or termination of the Study, return or otherwise dispose of any unused Study Treatment, at Vertex's expense and in accordance with written instructions from Vertex and Applicable Law. Institution shall maintain complete and accurate drug accountability records, and shall promptly provide such records to Vertex upon request. The Study Treatment shall be used solely in conducting the Study.

What goes in the contract?

- Payment terms – what and when you will be paid

4. *Payments Schedule*. The start-up and administrative fee will be paid upon execution of this Agreement. All other undisputed payments will be made in accordance with the Agreement and within forty-five (45) days following the end of each calendar quarter, based upon the number of visits completed as demonstrated by completion of entry of visit data in the eCRFs/CRFs. Institution shall complete the eCRFs/CRFs within five (5) days following a visit. The final payment is conditioned upon: (a) all enrolled subjects other than subjects discontinued or lost to follow-up having completed treatment in the Study as defined in the Protocol; (b) eCRFs/CRFs and Study Records for all subject visits performed having been completed and delivered to Vertex or designated CRO; (c) all unused Study Treatment having been returned or otherwise disposed of in accordance with Vertex's instruction and Applicable Law; and (d) all queries having been resolved to Vertex's satisfaction.

Invoicing

Develop a system for tracking all charges and events

Submit invoices for all of these items according to the time schedule outlined in the contract

Reconcile the payments with invoices on a periodic basis

Do not close the study account until you are assured you have received all payments

Sponsor Invoicing & Receivables

Communicate with your administrators!

- Who is responsible for invoicing? How often?
- Let them know when there is study activity = something to invoice
  - IRB amendments/renewals, screen failures, shipping, unscheduled visits, etc.
  - Recruitment

You negotiated a contract and did the work so collect the money!!!

Expense Monitoring

Corporate Clinical Studies are contracts, not grants

- You can only spend what you earn
- No enrollment = insufficient funds

Effort continues on clinical studies whether patients are being enrolled or not

- Screening
- Regulatory (documentation, amendments, continuing reviews)
- Sponsor communications

Important to monitor your expenses in relation to your income

- When to consider closing a study?

What if I fall behind in my revenues?

It is possible to have a negative balance

- You are paying out charges before you have had invoices paid
- Salary is most typically attributed to the grant and may not reflect actual activity (pay attention!)

Make sure that invoices have been sent out and that payments have been reconciled

If you cannot enroll, you should stop the study

Closing out a study

- When things are not going so well
- When we've completed the study
  - Are you sure we're done? (queries, monitor visits, etc.)
  - Have we invoiced for EVERYTHING?
  - Have we been paid what we invoiced?
- How did we do? Any contingency funds?
  - What do we do with them?

What if I have money left over?

It is possible for an industry study to realize a “profit”

- Your budget was “off” but you do not need to return the monies as you have a contract agreement with the sponsor
- Most likely because you are spending more time on the study but not charging personnel time to the grant

You can attribute additional salary to the grant, but only for those who have worked on the study (compliance issue)

After the study is closed, you may move the remaining funds (i.e. all expected charges have been paid) into a residual account

- This may be used like any other state funds
  - Salary
  - Travel
  - Academic costs

Final thoughts…

Budget/Contract Negotiations

- Always negotiate

Feasibility, Planning & Enrollment are key

- PI, Coordinator, Other research staff/experts, Data, Central office/CTO
- Recruitment plan & execution

How do we define success?

- Meeting contract obligations as outlined in the contract
- Expenses < Income = Contingency/Development funds
  - Projects with > 25% of the total project revenue may require explanation
  - http://academicdepartments.musc.edu/vpfa/policies/grants/4-4.02.htm