Planning & Budgeting for Clinical Trials

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of South Carolina

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Learning Objectives

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

1.) Understand the importance that your guidance on study implementation workflow has on supporting the budget development and negotiation process

2.) Identify what elements of a clinical research budget are negotiable

3.) Gain familiarity with the communication required to maximize clinical research revenue

MUSC Clinical Research Liaisons

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

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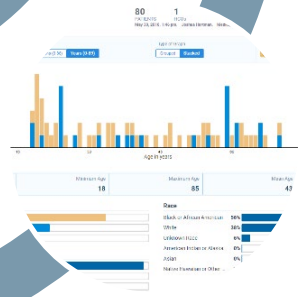
Research Opportunities & Collaborations (ROC)

Matching study opportunities with investigators

Study opportunities & Industry Partnerships

Investigator outreach & key research contacts



Feasibility & site selection support

IQVIA™

PPD®

ICON

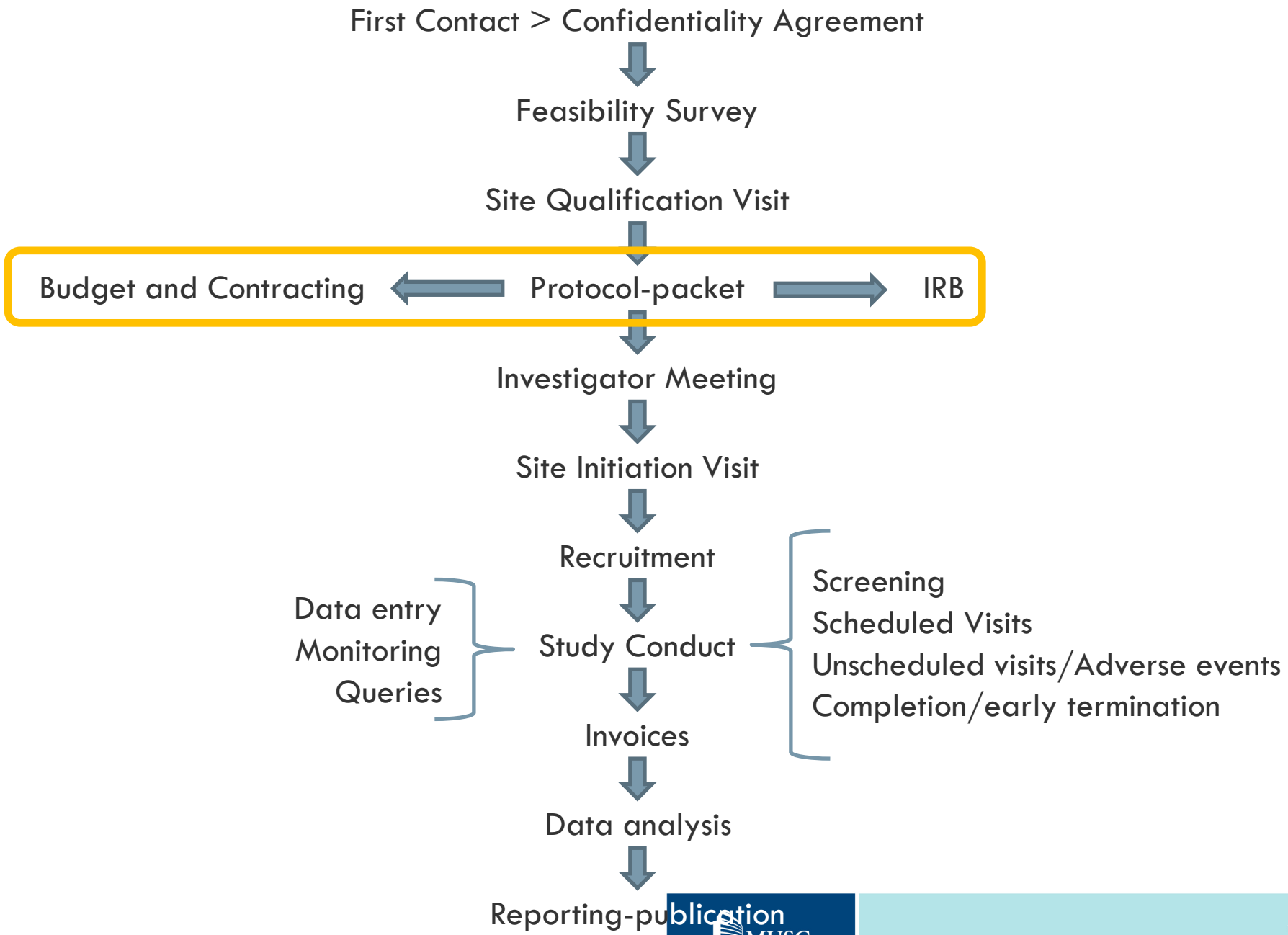
parexel®

TriNetX

TRIAL INNOVATION NETWORK

Budgeting Process

Feasibility & Planning	Sponsor & Internal Feasibility
Prospective Reimbursement Analysis	Who will pay for protocol procedures?
Internal Budget Development	Personnel, per patient costs, site level
Budget Negotiation	Negotiations and justification
IPF & Contract Negotiation / Execution	Internal routing & approvals


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
Reporting-publication

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!

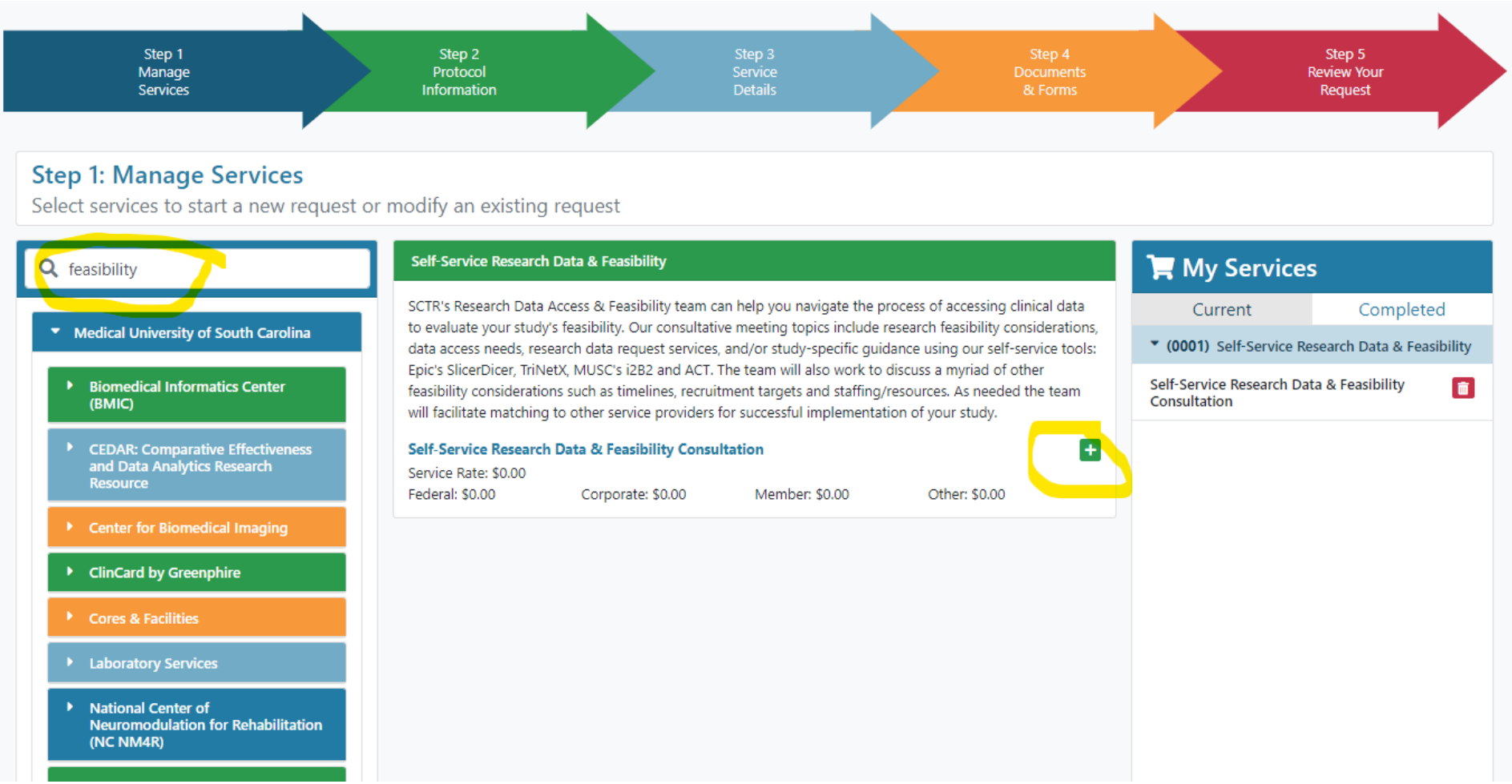
Self-Service Query Tools

Cogito ergo sum SlicerDicer

TriNetX

i2b2 Query & Analysis Tool

Self-Service Research Data & Feasibility Consultation Service



- 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

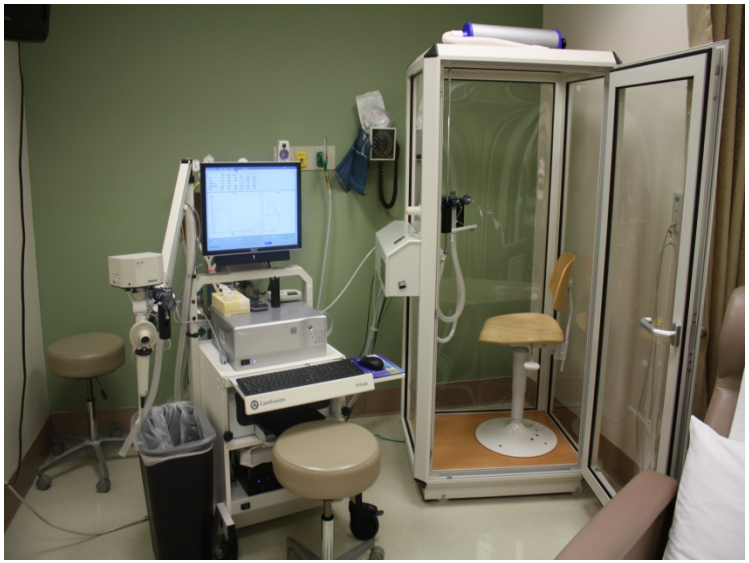
SCresearch.org

SCTR Research Nexus

Phase 1-4 Research Center & Hospital Provider Based Clinic

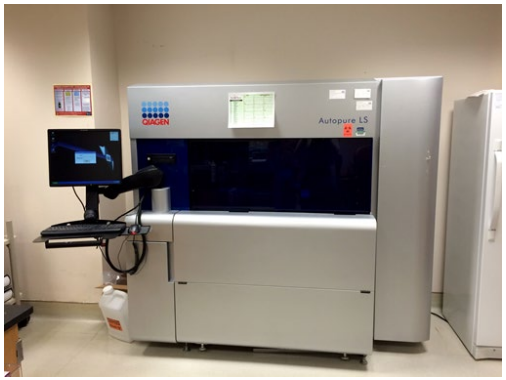
Outpatient, Inpatient & Mobile Nursing
Chemotherapy & Biotherapy Certified Nurses
Nutritionist

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

Comprehensive coverage analysis that

- Informs the budgeting process: routine care versus sponsor paying
- Sets up research billing calendar
- Is used for monitoring & auditing clinical research billing compliance

This Coverage Analysis sets out billing determinations based on insurance principles, using Medicare coverage rules. The billing determinations are not clinical instructions.

Protocol Related Items and Services		Location in Protocol	CPT / HCPCS Codes	Schedule of Procedures											General Comments	Coverage Determinations
					Treatment											
				Screening	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6 - Cycle 35	End of Treatment	Safety Follow-up	Follow-up (Q9W or Q12	Survival Follow-up	This study is a Qualifying Clinical Trial per NCD 310.1.	NCD 310.1; NCCN Guidelines Cervical Cancer version 3.2019; NCD 210.13; NCD 201.6; NCD 210.7; NCD 190.15; UptoDate: Tumor lysis syndrome: prevention and treatment; NCD 190.22; Investigator Brochure; UptoDate: Invasive cervical cancer: Staging and evaluation of lymph nodes
Visit Day and Window				-28 (27d)	1	22(+-3d)	43(+-3d)	64(+-3d)	85(+-3d)	106(+-3d)	At time of discontinuation	(+-7d)	(+-7d)	(+-7d)		
Is this an Outpatient (OP) or Inpatient (IP) visit?				OP	OP	OP	OP	OP	OP	OP	OP	OP	OP	OP		
Full Physical Exam		p. 80	99201-99205 or 99211-99215	T							T					Physical exam is part of the receipt of the conventional care services being performed during workup and treatment. Physical exam is clinically relevant during follow-up as it is recommended following treatment. Physical exam is a routine cost under NCD 310.1 as conventional care. There is not a NCD that addresses the use or limitations of physical exam. Palmetto GBA does not have a LCD that addresses
Directed Physical Exam		p. 80	99201-99205 or 99211-99215		T	T	T	T	T	T		T				
Vital Signs		p. 80	N/A	NB	NB	NB	NB	NB	NB	NB	NB	NB			Not separately billable from the E/M visit (physical exam).	
12-lead ECG		p. 81	93005 (tracing) and 93010 (report)	R							R					This test appears to be performed for data collection only as it is indicated at Screening and EOT only. Test/services performed solely for the purpose of research are not allowable costs and should not be billed to the participant/third-party payer.
CT Chest		p. 73-76	71250 or 71260 or 71270	R				R		R*	R		R		*Per protocol, p. 21: Perform imaging within 28 days prior to randomization. On tratement, perform imaging Q9W through Wk. 54, then perform imaging Q12W therafter. Per protocol, p. 75, for Second Course (Retreatment): The first on-study imaging assessment should be performed at 12 weeks after the restart of treatment. Subsequent tumor imaging should be performed every 12 weeks or more frequently if clinically indicated.	
Laboratory Procedures	Pregnancy Test (urine or serum)	p. 81	81025 or 84702	R											Per protocol p. 81: Pregnancy testing must be performed within 72 hrs of randomization. If urine test is positive or not evaluable, a serum test will be required. Monthly testing is only required per local regulations.	This service appears to be performed regardless of signs or symptoms. Diagnostic tests absent signs or symptoms are not covered by Medicare except in limited circumstances not applicable here.
	PT/INR	p. 116	85610	R												This service is provided by the Sponsor free of charge to the participant according to the study budget.
	aPTT/PTT	p. 116	85730	R												This service is provided by the Sponsor free of charge to the participant according to the study budget.
																Complete blood count with differential (CBC) includes hemoglobin, hematocrit, red blood cell count, mean cell volume, mean cell hemoglobin, mean cell hemoglobin concentration, white blood cell count with differential,

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:

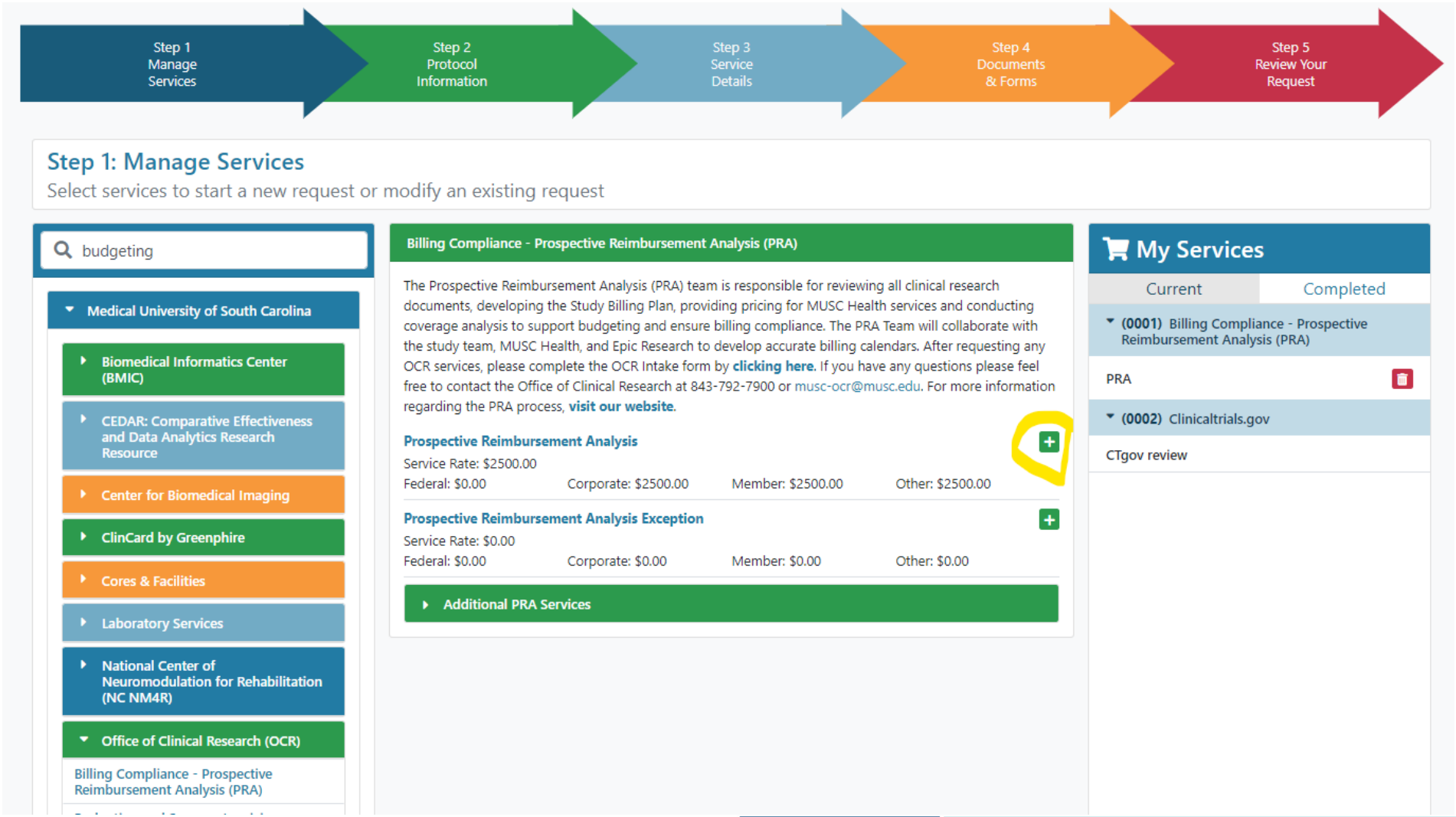
1. Billing for services already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial

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 Service is requested in SPARCRequest®

Regulatory and start up packet, essential documents required

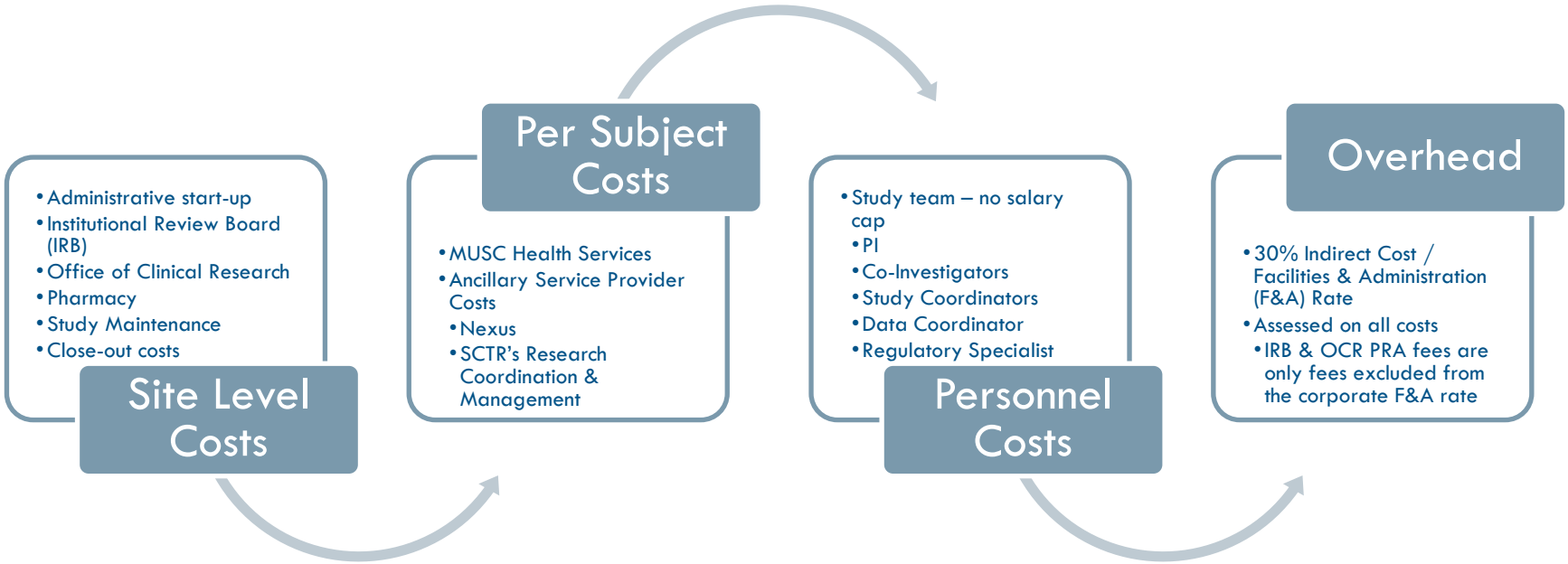
Prospective Reimbursement Analysis



Budget Categories

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

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:

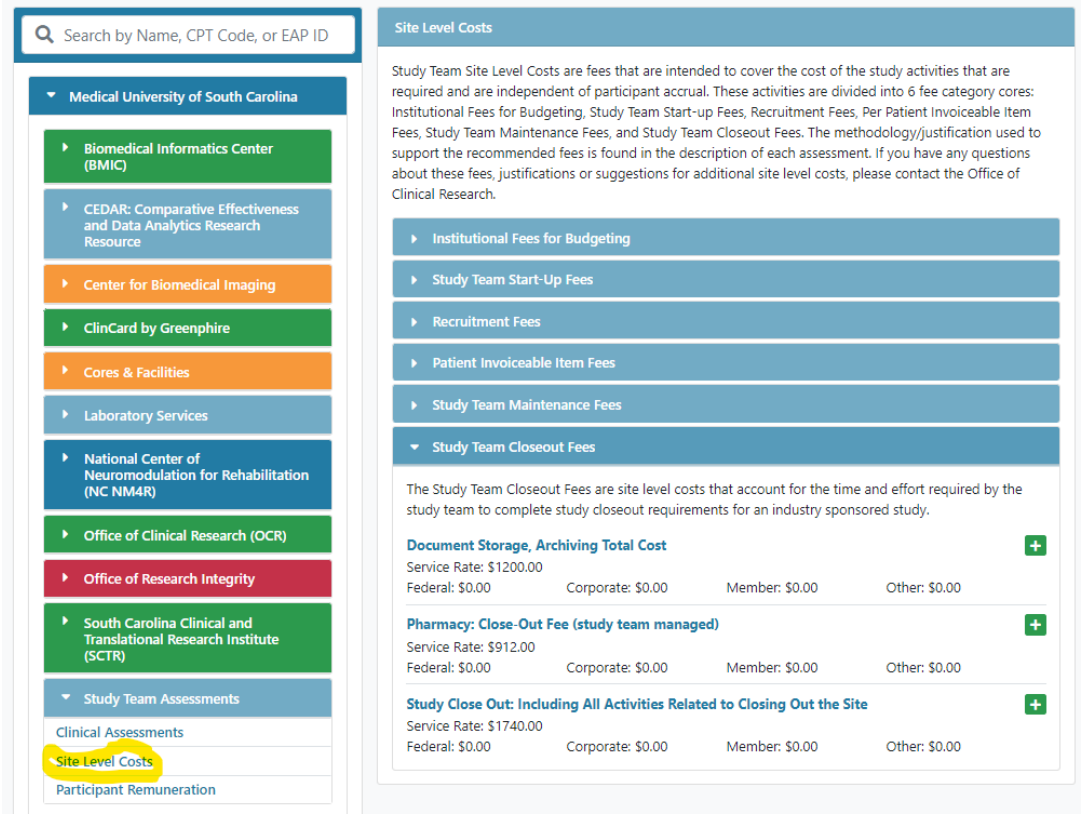
- Study Drug Storage
- Freezer storage
- Record storage
- Monitor change fee
- Close out costs
- Etc.

These are often listed itemized as invoiceable costs

Site Level Costs

These are the costs 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



Site Level Costs – Sponsor Offer

Site Costs	
	Cost
Archiving/Document storage/per site	735.00
Site Start-up Costs	6,000.00

Overhead fees will be charged in accordance with the Budget or attached hereto. IRB/EC review fees will be reimbursed to Institution upon receipt of original IRB/EC invoice. No additional amount shall be paid hereunder for any costs, expenses, fees, or other liabilities unless expressly agreed in advance by the Parties in writing.

Site Level Costs – Actual

Startup and Study maintenance costs, such as:

- IRB fees and staff prep costs
- OCR PRA Costs
- OCR Budgeting & Invoicing
- Radiology set up
- Ancillary Department Training
- No Study Drug Storage – long term efficacy study
- Record storage
- Monitoring visit staff time
- Close out costs
- SAE reporting
- Re-consenting

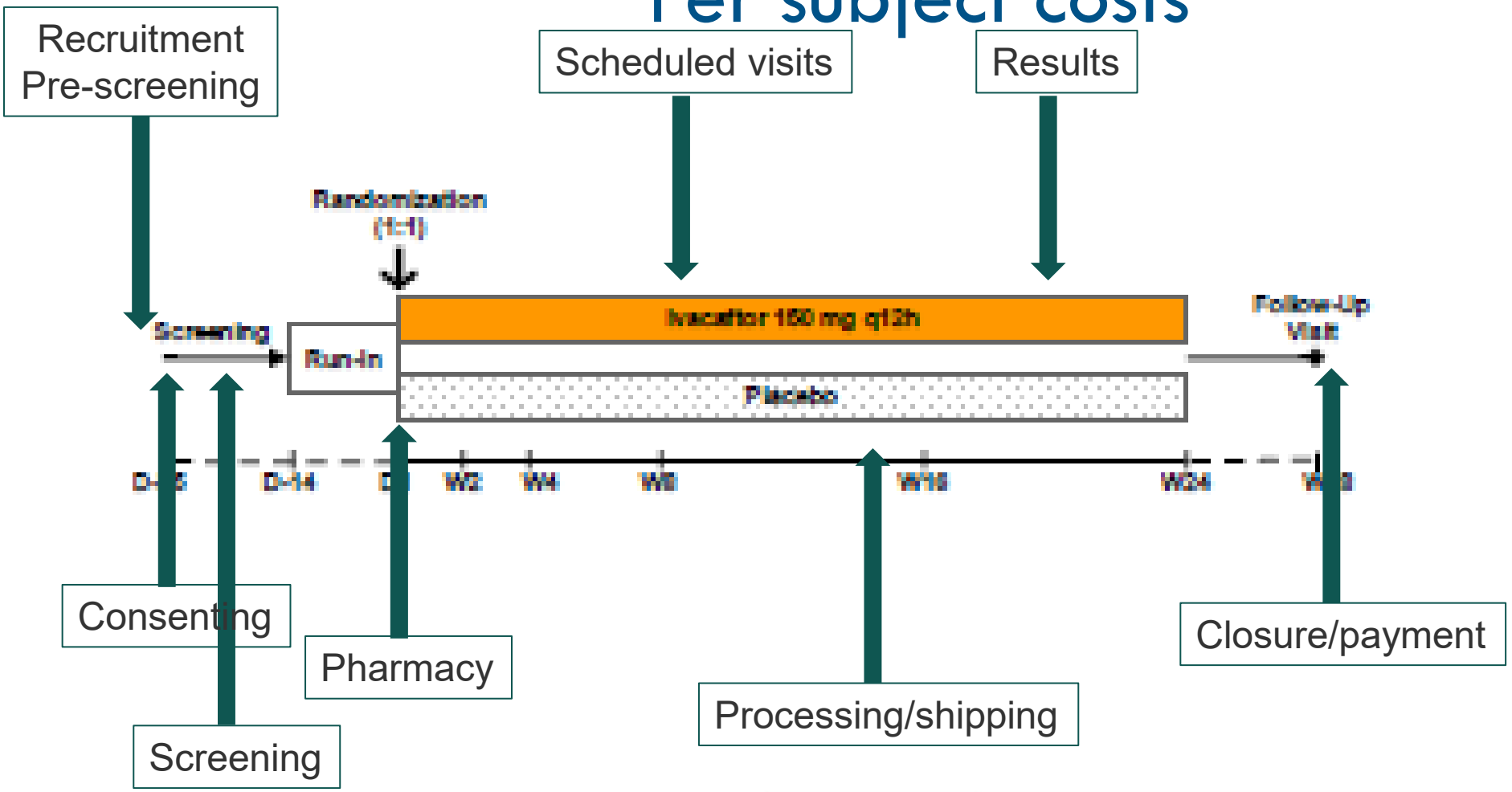
Site Level Costs – Internal Budget

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	$ 2,500.00	$ 2,500.00	$ 2,500.00	1	N	$ 2,500.00	$ -
Prospective Reimbursement Analysis (PRA) Amendment Fee	$ 1,000.00	$ 1,000.00	$ 1,000.00	1	N	$ 1,000.00	$ -
OCR Clinical Research Management Fee	$ 2,750.00	$ 2,750.00	$ 2,750.00	1	Y	$ 3,575.00	$ -
IRB Initial Review	$ 2,500.00	$ 2,500.00	$ 2,500.00	1	N	$ 2,500.00	$ -
IRB Amendment	$ 500.00	$ 500.00	$ 500.00	1	N	$ 500.00	$ -
IRB Continuing Review	$ 750.00	$ 750.00	$ 750.00	6	N	$ 4,500.00	$ -
Study Start-Up Fee/Site Set-Up Fee	$ 9,540.00	$ 9,540.00	$ -	1	Y	$ 12,402.00	$ 9,540.00
Developmental Pediatrics Protocol Training Costs		$ 1,500.00	$ 1,500.00	1	Y	$ 1,950.00	$ -
Level 1 Annual Study Maintenance Fee (billing compliance, sponsor/CRO correspondence, ongoing	$ -	$ 2,769.23	$ 775.00	6	Y	$ 21,600.00	$ 11,965.38
IRB/Contracting document preparation fee for amendments, contract/budget amendments, per sub	$ 1,000.00	$ 1,000.00	$ -	6	Y	$ 7,800.00	$ 6,000.00
Daily Monitoring Visit Fee (remote or onsite)	$ -	$ 500.00	$ -	1	Y	$ 650.00	$ 500.00
Site Audit, Quality Audit, Clinical Trial Master File Audit, per day		$ 1,230.77	$ -	1	Y	$ 1,600.00	$ 1,230.77
Re-Consent, Informed Consent Performed Again with the Same Patient	$ 117.00	$ 86.15	$ -	1	Y	$ 112.00	$ 86.15
IND Safety Report Fees for PI Review (per report)		$ 21.54	$ -	1	Y	$ 28.00	$ 21.54
Serious Adverse Event Reporting Fee		$ 288.46	$ -	1	Y	$ 375.00	$ 288.46
Study Staff Training/ Inservice		$ 462.00	$ -	1	Y	$ 600.60	$ 462.00
Document Storage, Archiving Total Cost	$ 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	$ 1,740.00	$ 1,740.00	$ -	1	Y	$ 2,262.00	$ 1,740.00
Radiology Set Up Fee	$ 975.00	$ 975.00	$ 390.00	1	Y	$ 1,267.50	$ 585.00
Study Level Services: Total Cost						**$ 66,782.10**	**$ 33,619.31**

Site Level Costs – Final

Site Costs	
	Cost
Archiving/Document storage/per site	1560.00
Site Start-up Costs	12402.00
Prospective Reimbursement Analysis	2500.00
Prospective Reimbursement Analysis (PRA) Amendment Fee	1000.00
OCR Clinical Research Management Fee	3250.00
Imaging Protocol Review (Level 2)	1267.50
Study Staff Training/In-servicing Fee	600.60
Re-Consent, Informed Consent Performed Again with the Same Patient	152.00
Serious Adverse Event Reporting Fee	375.00
Annual Study Maintenance Fee (billing compliance, sponsor/CRO correspondence, ongoing patient screening/retention, training, administrative costs, etc.)	3600.00
Daily Monitoring Visit Fee	650.00
IND Safety Report Fees for PI Review (per report)	28.00
IRB Document Study Team Preparation Fee for Amendments, Continuing Reviews, Termination	1300.00
Initial Protocol Review	Pass through
Continuing Review	Pass through
IRB Amendment	Pass through
Developmental Pediatrics Protocol Training Costs	1950.00
Site Audit, Quality Audit, Clinical Trial Master File Audit	1500.00
Study Close Out: Including All Activities Related to Closing Out the Site	2262.00

Per subject costs



Per Subject Costs: Events During Study

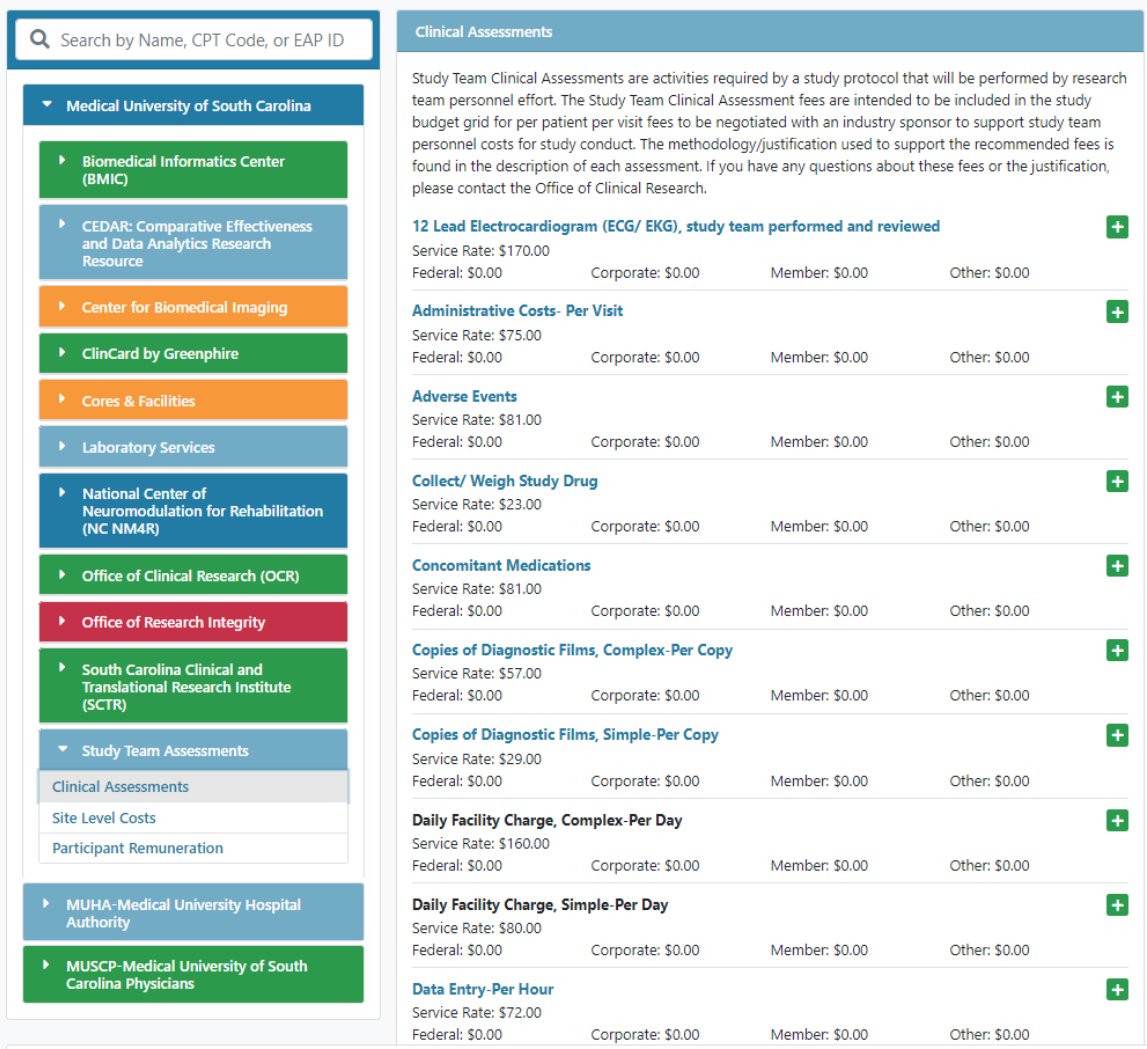
SCHEDULE of EVENTS

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



OCR Participant Remuneration

Happy Participants, Happy Study Team, Happy Institution

- Participants receive remuneration in a timely manner
- Study team & accounts payable's burden reduced
- Streamlined IRS compliance & adherence to reporting guidelines

ClinCard
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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

Sponsor Per Patient – Proposal

Budget Information

Total Cost per Patient:	6,549.38	**PI:**	
Overhead Percent:	25.00%	**Institution:**	
Country:	US		
Currency:	USD		

Study Week		12 mo + 2 wk	18 mo +/- 6 wk	24 mo +/- 6 wk	30 mo +/- 6 wk	3 yr +/- 6 wk	3 .5 yr +/- 6 wk	4 yr +/- 6 wk	4.5 yr +/- 6 wk	5 yr +/- 6 wk
		Clinic	Phone	Clinic	Phone	Phone	Phone	Phone	Phone	Clinic
Study Procedure	**Cost**									
Informed Consent	113.00	113.00								
Eligibility Criteria	53.00	53.00								
Initial Visit (Demographics, Medical History, Length, Height, Body weight, Head Circumference, Physical Examination, Blood pressure, heart rate, respiratory rate)	212.00	212.00								
Follow up visit (Length, Height, Body weight, Head Circumference, Physical Examination, Blood pressure, heart rate, respiratory rate, visual acuity)	140.00			140.00						140.00
BSID (or KPSD)	30.00			30.00						30.00
WPPSI	60.00									60.00
GMFM-88	38.00			38.00						28.50
VABS	40.00			40.00						40.00
ADHD-RS	44.00									44.00
SCQ	38.00									38.00
CIQ	16.00	16.00		16.00						16.00
Vision and hearing assessment history	50.00		50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00
Pulmonary morbidity assessment (in clinic or by phone interview)	44.00	INV	44.00	44.00	44.00	44.00	44.00	44.00	44.00	44.00
Cerebral MRI (optional)	INV									INV
Spirometry (optional)	INV									INV
EQ-5D-5L	25.00			25.00		25.00		25.00		
PedsQL	27.00			27.00		27.00		27.00		27.00
HCRU	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00
HUI2/3	49.00									49.00
Assessment of participation in other clinical studies, medications, procedures, therapies	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00
Adverse Events	38.00	38.00	38.00	38.00	38.00	38.00	38.00	38.00	38.00	38.00
Staff Fees										
Physician's Fees without Exam Costs	173.00	173.00		173.00						173.00
Study Coordinator Fee Per Visit	171.00	171.00	171.00	171.00	171.00	171.00	171.00	171.00	171.00	171.00

Visit Subtotal		**865.00**	**392.00**	**881.00**	**392.00**	**444.00**	**392.00**	**444.00**	**392.00**	**1,037.50**
Overhead (per visit)	**25%**	**216.25**	**98.00**	**220.25**	**98.00**	**111.00**	**98.00**	**111.00**	**98.00**	**259.38**
Total Per Visit (w/ OH)		**1,081.25**	**490.00**	**1,101.25**	**490.00**	**555.00**	**490.00**	**555.00**	**490.00**	**1,296.88**

	6,549.38

Sponsor Per Patient – Final

Budget Information

Total Cost per Patient:	12,010.70	**PI:**	Dr. Carol Wagner
Overhead Percent:	30.00%	**Institution:**	Medical University of South Carolina
Country:	US		
Currency:	USD		

Study Week		12 mo + 2 wk	18 mo +/- 6 wk	24 mo +/- 6 wk	30 mo +/- 6 wk	3 yr +/- 6 wk	3 .5 yr +/- 6 wk	4 yr +/- 6 wk	4.5 yr +/- 6 wk	5 yr +/- 6 wk
		Clinic	Phone	Clinic	Phone	Phone	Phone	Phone	Phone	Clinic
Study Procedure	**Cost**									
Informed Consent	174.00	174.00								
Eligibility Criteria	117.00	117.00								
Initial Visit (Demographics, Medical History, Length, Height, Body weight, Head Circumference, Physical Examination, Blood pressure, heart rate, respiratory rate)	326.00	326.00								
Follow up visit (Length, Height, Body weight, Head Circumference, Physical Examination, Blood pressure, heart rate, respiratory rate, visual acuity)	197.00			197.00						197.00
BSID (or KPSD)	306.00			306.00						
WPPSI	262.00									262.00
GMFM-88	188.00			188.00						141.00
VABS	181.00			181.00						181.00
ADHD-RS	154.00									154.00
SCQ	46.00									46.00
CIQ	23.00	23.00		23.00						23.00
Vision and hearing assessment history	72.00		72.00	72.00	72.00	72.00	72.00	72.00	72.00	72.00
Pulmonary morbidity assessment (in clinic or by phone interview)	112.00	INV	112.00	112.00	112.00	112.00	112.00	112.00	112.00	112.00
Cerebral MRI (optional)	INV									INV
Spirometry (optional)	INV									INV
EQ-5D-5L	28.00			28.00		28.00		28.00		
PedsQL	46.00			46.00		46.00		46.00		46.00
HCRU	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00	49.00
HUI2/3	49.00									49.00
Assessment of participation in other clinical studies, medications, procedures, therapies	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00
Adverse Events	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00	81.00
Staff Fees										
Physician's Fees without Exam Costs	320.00	320.00		320.00						320.00
Study Coordinator Fee Per Visit	228.00	228.00	228.00	228.00	228.00	228.00	228.00	228.00	228.00	228.00

Visit Subtotal		**1,399.00**	**623.00**	**1,912.00**	**623.00**	**697.00**	**623.00**	**697.00**	**623.00**	**2,042.00**
Overhead (per visit)	**30%**	**419.70**	**186.90**	**573.60**	**186.90**	**209.10**	**186.90**	**209.10**	**186.90**	**612.60**
Total Per Visit (w/ OH)		**1,818.70**	**809.90**	**2,485.60**	**809.90**	**906.10**	**809.90**	**906.10**	**809.90**	**2,654.60**

12,010.70

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:	11111						
RMID:	1111						
Short Title:	Short Title						
Protocol Title:	Full protocol title						
Sponsor:	Pharma Company						
Primary PI Name:	Dr. Principal Investigator						
Business Manager:	Department Financial Contact						
Funding Source:	Industry-Initiated/Industry-Sponsored						
Indirect Cost Rate:	30%						
Staff Fringe Rate:	42.8%						
Authorized Users							
Name	**Role**	**Institutional Bas**	**% Effort**	**Project Period (in months)**	**Salary Requested**	**Fringe**	**Total**
Principal Investigator	Primary PI	$ 200,000.00	0.50%	84	$ 7,000.00	$ 2,996.00	$ 9,996.00
Research Coordinator - TBD	General Access User	$ 50,000.00	10%	84	$ 35,000.00	$ 14,980.00	$ 49,980.00
Total					**$ 42,000.00**	**$ 17,976.00**	**$ 59,976.00**

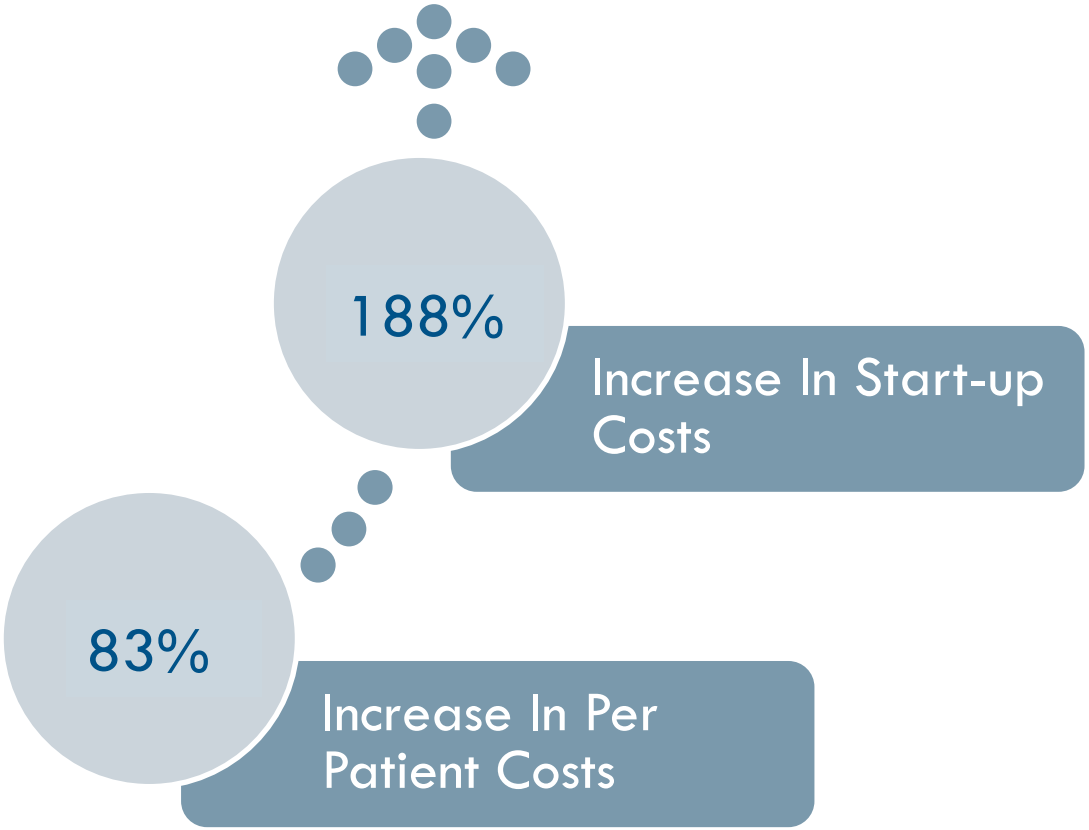
Breakeven Analysis

Formula assumptions:

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

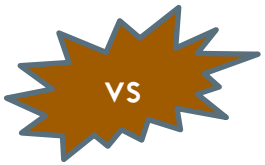
Study Budget		
Total Study Cost (Sponsor Cost)	$	138,846.30
Total Margin	$	87,973.31
Study Contingency	$	27,997.31
Breakeven Analysis		3
Total Budget	$	138,846.30

Case Study: Budgeting Impact



Internal Budget

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



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

OCR Finance Website Resources

Log Out | Visit Other MUSC Sites | MyQuest

MUSC Medical University of South Carolina

Office of Clinical Research

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

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

Budget Negotiations

Tips for Successful Budget Negotiations

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 and to use key skills such as advanced planning, preparation and patience. Below are some tips to ensure a successful negotiation:

1. **Create an internal budget**. After reviewing the study's protocol and initial sponsor budget, create an internal version of the budget to ensure all assessments and costs are accounted for and personnel costs and study fees are captured.

2. **Know your true costs and breakeven.** It is essential that you know the true cost of your study before starting negotiations. Use your internal budget to find the number of patients you need to enroll to breakeven and have enough revenue to cover your true costs. This is a good point to evaluate if the study is right for your team based on the true cost and number of patients it is realistic to enroll.

3. **Leave room to negotiate**. Keeping your true costs and breakeven in mind, make sure you leave room to negotiate/meet in the middle.

4. **Be prepared to justify your costs.** It is important to keep in mind that sponsors can, and often will, ask you to justify certain costs on your budget and you will need to be prepared to provide them with that justification. Sponsors are often looking for justification that the fees our site is requesting are aligned with Fair Market Value (FMV). This link can will provide you with justification language samples to assist you with this part of the process.

5. **Negotiate using the sponsor's budget format.** Once you have completed the internal budget and financial analysis, translate that information into the sponsor's budget format. By doing this, you can help your sponsor contact understand your changes and may help expedite their review and revisions.

Did you know that the OCR Finance Team is available on a fee for service basis to handle your budget negotiation process for you?

For more information about OCR Finance Team services visit the Finance Team website or contact the Office of Clinical Research at 843-792-7900 or OCRbudgeting@musc.edu.

Justification Documentation

Version: 1.4 - Date: 05/01/2020

MUSC
Medical University of South Carolina

Office of Clinical Research
Office of the Vice President for Research
Suite 170, 125 Doughty Street, MSC 195
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

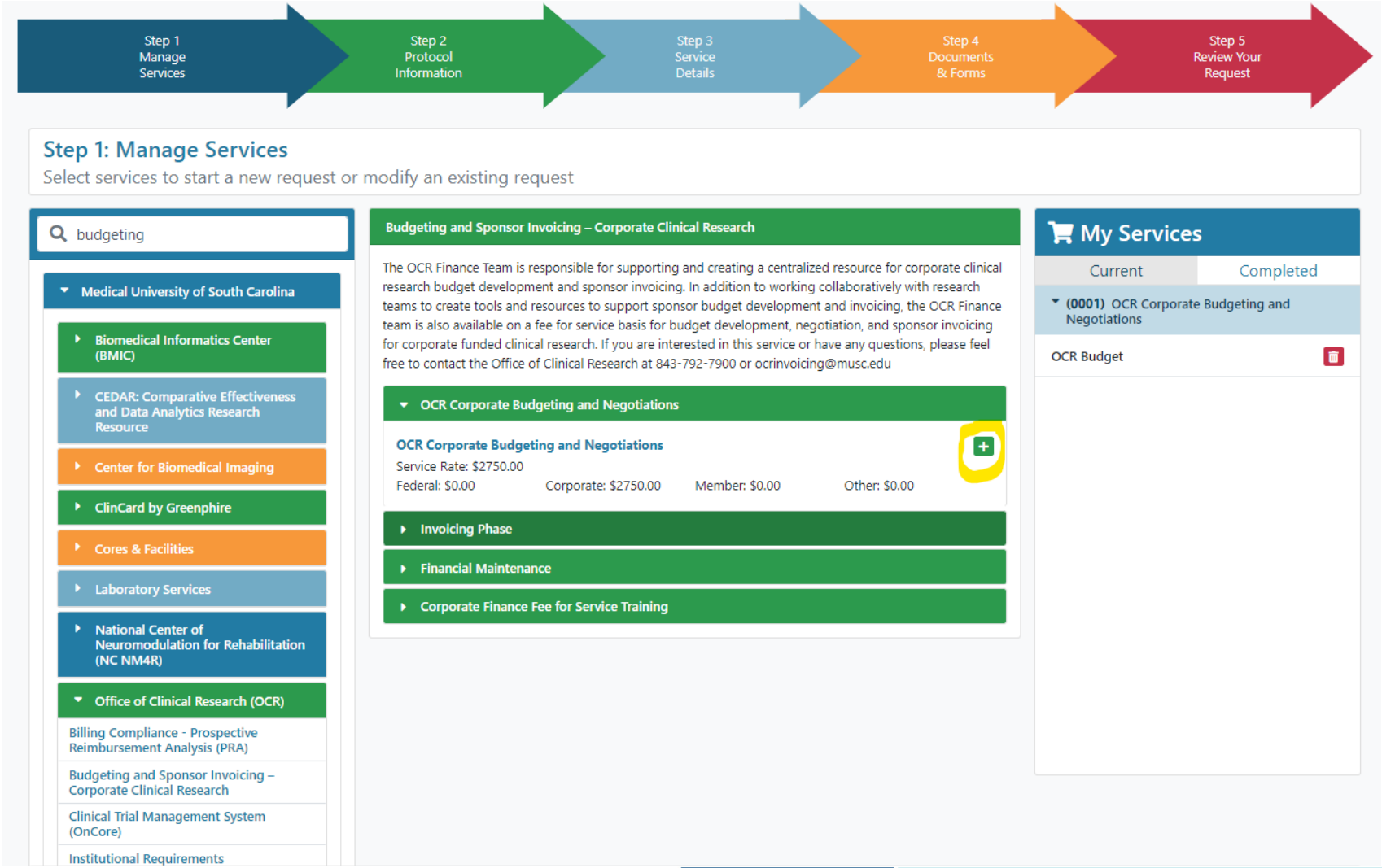
The IRB Initial Protocol Review fee of $2500 is charged upon initial submission for IRB review by MUSC.

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

The IRB Amendment fee of $500 is charged for IRB amendments submitted for review.

- 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.)

Corporate Budgeting & Negotiations Service



- Route completed budget and CTA document in Cayuse IPF 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 – now Oncore Clinical Trials Management System (CTMS)
- Submit invoices for all 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

Budgeting & Invoicing – CTMS

Procedure Toggle Full Screen	Treatment				Follow Up	
	Pre procedure (Screening /Baseline) 1@1Days	Procedure 1@1Days	24 (-6/+24) hrs. post procedure 1@1Days	Discharge (or Day 5-7 whichever comes first) 1@1Days	30 and 90 day Follow Up	
	Pre procedure (Screening /Baseline)	Procedure	24 (-6/+24) hrs. post procedure	Discharge (or Day 5-7 whichever comes first)	Day 30	Day 90
Visit Fee	R	R	R	R	R	R

	Amount		Payment			
Invoice Date	Total	After Withheld	Check No.	Amount	Date	V
11/22/2019	12,750.00	12,750.00	ACH payment	12,750.00	12/31/2019	
11/30/2019	19,540.00	19,540.00	ACH payment	19,540.00	01/15/2020	
03/31/2020	23,730.00	23,730.00	ACH payment	23,730.00	04/02/2020	
05/31/2020	58,670.00	58,670.00	ACH payment	58,670.00	07/21/2020	
08/31/2020	17,324.00	17,324.00	ACH payment	17,324.00	10/06/2020	
01/05/2021	44,814.00	44,814.00	ACH payment	44,814.00	01/11/2021	
02/28/2021	15,890.00	15,890.00	ACH payment	15,890.00	04/26/2021	
	192,718.00	**192,718.00**		**192,718.00**		

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