The Ohio State University Medical Center

Key Considerations: Internal Budgets for Industry Sponsored Clinical Trials

11/25/08

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Research Billing Office

The Ohio State University Medical Center

Objectives

- Identify the difference between Internal and Sponsor Budgets
- Identify Core Components for Industry Sponsored Clinical Trial Internal Budgets
- Use “OSUMC Industry Sponsored Internal Budget template” to develop a sample budget
- Identify keys to negotiating payment terms and billing compliance

Definitions & General Considerations

- **Internal Budgets** = Used to identify all costs a site will incur to conduct a clinical trial.
  - Internal Budgets should not be sent to the sponsor. They should be used as a tool to develop the Sponsor Budget.

- **Sponsor Budgets** = Used to negotiate with the sponsor as part of the Clinical Trial Agreement.
  - If the sponsor funding is less than the cost to conduct the study a site either has to refuse the study or come up with alternate funding.

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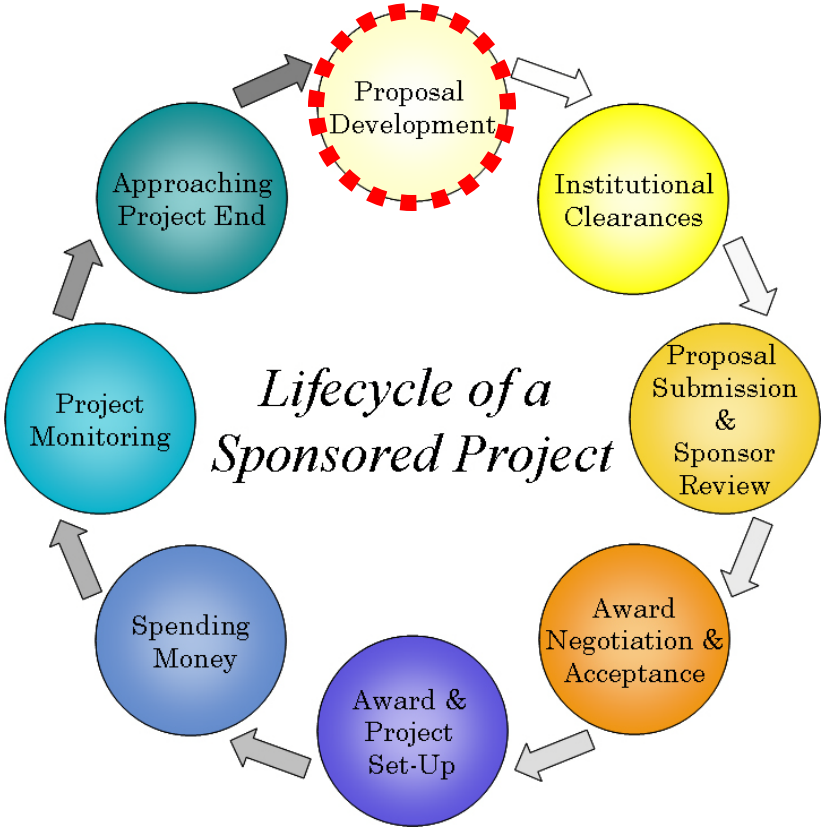
Questions that need answered

- How much will the trial cost to conduct?
- Does the sponsor's proposed budget cover costs? If not:
  - Will the sponsor negotiate payment to cover costs?

  OR

  - Is the study worth subsidizing? Who will subsidize? Will your department cover the expenses? Who will approve?

Developing the Budget is the Start of the Project Lifecycle



Lifecycle from OSU Research Foundation

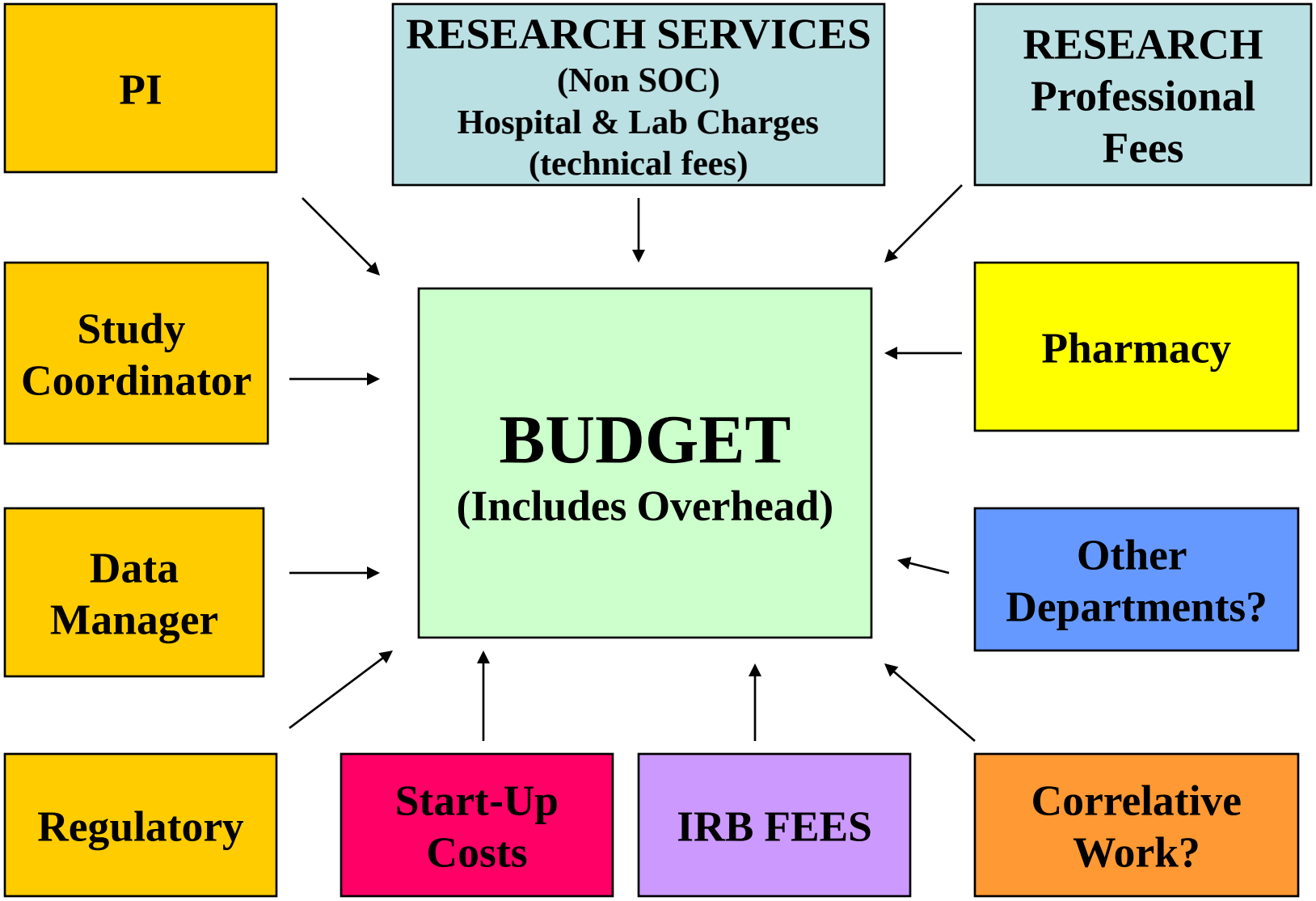
Budgeting Considerations

- One size does not fit all
  - Many different types of studies
  - Many different sponsors

  ….All have different budgeting needs….

- Key:
  - There are common core components to building budgets for all studies

CORE Budget Components



Adapted from:
The Ohio State University Comprehensive Cancer Center Office of Contract Development & Coordination

Budgeting Steps

1. Determine full cost to conduct study
   - Review Protocol, Contract, Consent & Case Report Forms to identify each procedure, visit, participant contact, supply items & professional fees that are needed to conduct the study
   - Separate items into Research or Standard of Care Charges
   - List items in Internal Budget
   - Include Start Up and Pass Through Items
2. Compare internal budget to sponsor budget
3. Negotiate when necessary
4. Coordinate subsidizing agreements when necessary
5. Monitor Budget & Payment

Start with Internal Budget Template

Available on the Research Billing Office Website

Protocol Budget Calendar

Contract No:	**Protocol No:**	**Department:**	**Sponsor:**
Protocol Target Accrual:	**PI:**	**Accrual to Date:**	
Study Title:			

A. PER PARTICIPANT / PER ARM COSTS

	Schedule of Events										
	Standard of Care (SOC) Vs. Research (R)	Screen	Visit 1/ Day 0	Visit 2/ Day 1	Visit 3 / Mth 1	Visit 4 / Mth 3	Visit 5 / Mth 6	Visit 6 / Yr 1	Visit 6 / Yr 2	Final Visit / Yr 3	Row Totals
ITEMS & SERVICES											
Informed Consent											$0.00
Inclusion/Exclusion											$0.00
Chart Review											$0.00
Medical History											$0.00
Physicial Exam											$0.00
Vital Signs											$0.00
Concominant Meds											$0.00
A/E Reporting											$0.00
Clinic Visit											$0.00
Pharmacy Fees											$0.00
X-Rays & Scans (ex. MRI)											$0.00
EKG											$0.00
Procedures (ex. Cath)											$0.00
Drug Accountability Logs											$0.00
Laboratory Tests (ex. CK-MB)											$0.00
Professional Fees (ex. EKG Rd)											$0.00
Study Coordinator Time											$0.00
PI Time											$0.00
Supplies (ex. Dry ice)											$0.00
Participant Stipends											$0.00
Participant Travel/Parking											$0.00
Other:											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
Sub-Total PerPparticipant Costs		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Plus F&A Overhead Rate		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
TOTAL PER PARTICIPANT COSTS		**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Calendar Foot Notes:

Current F&A rate	**26%**

Note: A Coverage Analysis should be performed to assist with making SOC determinations. See the Research Billing Office Website for instructions.

TIPS: 1. Enter SOC in fields where the test is deemed to be standard regardless of participation in the study. 2. Enter the Cost for services that are Research. Research services should not be billed to insurance. The research charges will make up the per participant budget for the study. 3. Overhead rates change periodically. Click on Overhead Rate for link to OSU's "Rate Agreement" for full cost. College of Medicine 2008 approved rate is 26%. Remember to change percentage in cell B43 when rate changes.

Identify what work is required per PARTICIPANT

Protocol Budget Calendar

Contract No: 10000 **Protocol No:** XYZ **Department:** Research **Sponsor:** Pharma

Protocol Target Accrual: 10 **PI:** Investigator, Principal **Accrual to Date:** Assessment

Study Title: SAMPLE: Phase II, Double-Blind, Placebo-Controlled, Randomized, Multicenter Efficacy trial of XXX in participantss w ith acute decompensated ischemic congenstive heart failure.

A. PER PARTICIPANT / PER ARM COSTS

	Schedule of Events										
	Standard of Care (SOC) Vs. Research (R)		Visit 1/ Day 0 = Hosp IP	Visit 2/ Day 1	Visit 3 / Mth 1	Visit 4 / Mth 3	Visit 5 / Mth 6	Visit 6 / Yr 1 = Final Visit			Row Totals
ITEMS & SERVICES											
Informed Consent			X								$0.00
Inclusion/Exclusion			X								$0.00
Chart Review			X								$0.00
Medical History			X								$0.00
Physicial Exam*			X		X	X	X	X			$0.00
Vital Signs			X	X	X	X	X	X			$0.00
Concominant Meds			X	X	X	X	X	X			$0.00
A/E Reporting				X	X	X	X	X			$0.00
Clinic Visit					X	X	X	X			$0.00
Pharmacy Fees			X		X	X	X	X			$0.00
Chest X-Ray			X				X	X			$0.00
EKG			X	X	X	X	X	X			$0.00
Cardiac Angiogram			X					X			$0.00
Drug Accountability Logs			X		X	X	X	X			$0.00
CK-MB			X	X	X	X	X	X			$0.00
EKG Professional Read			X	X	X	X	X	X			$0.00
Study Coordinator Time			X	X	X	X	X	X			$0.00
PI Time*			X	X		X	X	X			$0.00
Dry Ice			X	X			X	X			$0.00
Participant Stipends					X	X	X	X			$0.00
Participant Travel/Parking					X	X	X	X			$0.00
Central Lab Processing Time			X	X			X	X			$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
Sub-Total Per Participant Costs		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Plus F&A Overhead Rate		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
TOTAL PER PARTICIPANT COSTS		**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Customize per Protocol

Mark when Items are Required

Calendar Foot Notes: Mth 1 PE is abbreviated. To be performed by study RN

Current F&A rate 26%

Identify what is Research vs. Standard of Care

RESEARCH SERVICES =

Services that are not typically performed in the Participant population or are performed strictly for research purposes.

Billed to Study/Sponsor

Build into Study Budget

STANDARD OF CARE =

Services that are typically performed in the Participant population for the disease being studied

Billed to Participant/Insurance

Note: Standard/Routine care should meet the definition outlined in Medicare's Clinical Research Policy. See "Steps to Performing a Coverage Analysis" on the RBO Website

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Mark Research and SOC in Internal Budget Template

(Section A)

Protocol Budget Calendar

Contract No: 10000 **Protocol No:** XYZ **Department:** Research **Sponsor:** Pharma

Protocol Target Accrual: 10 **PI:** Investigator, Principal **Accrual to Date:** Assessment

Study Title: SAMPLE: Phase II, Double-Blind, Placebo-Controlled, Randomized, Multicenter Efficacy trial of XXX in participants with acute decompensated ischemic congenstive heart failure.

A. PER PARTICIPANT / PER ARM COSTS

		Schedule of Events								
	Standard of Care (SOC) Vs. Research (R)		Visit 1/ Day 0 = Hosp IP	Visit 2/ Day 1	Visit 3 / Mth 1	Visit 4 / Mth 3	Visit 5 / Mth 6	Visit 6 / Yr 1 = Final Visit			Row Totals
ITEMS & SERVICES											
Informed Consent			R								$0.00
Inclusion/Exclusion	R		R								$0.00
Chart Review	R		R								$0.00
Medical History	R		R								$0.00
Physicial Exam*	SOC & R		SOC		R	SOC	SOC	SOC			$0.00
Vital Signs	SOC & R		SOC	SOC	R	SOC	SOC	SOC			$0.00
Concominant Meds	R		R	R	R	R	R	R			$0.00
A/E Reporting	R			R	R	R	R	R			$0.00
Clinic Visit	SOC & R				R	SOC	SOC	SOC			$0.00
Pharmacy Fees	R		R		R	R	R	R			$0.00
Chest X-Ray	SOC & R		SOC				SOC	SOC			$0.00
EKG	SOC & R		SOC	R	R	R	R	SOC			$0.00
Cardiac Angiogram	SOC & R		SOC					R			$0.00
Drug Accountability Logs	R		R		R	R	R	R			$0.00
CK-MB	SOC & R		SOC	SOC	R	R	R	R			$0.00
EKG Professional Read	SOC & R		SOC	R	R	R	SOC	SOC			$0.00
Study Coordinator Time	R		R	R	R	R	R	R			$0.00
PI Time*	R		R	R		R	R	R			$0.00
Dry Ice	R		R	R			R	R			$0.00
Participant Stipends	R				R	R	R	R			$0.00
Participant Travel/Parking	R				R	R	R	R			$0.00
Central Lab Processing Time	R		R	R			R	R			$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
Sub-Total Per Participant Costs		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Plus F&A Overhead Rate		$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
TOTAL PER PARTICIPANT COSTS		**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Some items may be SOC at one time point but Research at Others

Calendar Foot Notes: Mth 1 PE is abbreviated. To be performed by study RN

Current F&A rate 26%

Note: A Coverage Analysis should be performed to assist with making SOC determinations. See the Research Billing Office Website for instructions.

TIPS: 1. Enter SOC in fields where the test is deemed to be standard regardless of participation in the study. 2. Enter the Cost for services that are Research. Research services should not be billed to insurance. The research charges will make up the per patient budget for the study. 3. Overhead rates change periodically. Click on Overhead Rate for link to OSU's "Rate Agreement" for full cost. College of Medicine 2008 approved rate is 26%. Remember to change percent in cell R43 when rate changes.

Identify Fixed Costs

- Fixed costs are non-negotiable cost that have to be paid during the course of the study
- Examples of Fixed Costs
  - Laboratory testing, Procedures, Supplies, Pharmacy Charges, Dry ice, Shipping fees, Professional Fees
- Use the Research Operations Web Application (ROWA) to get Health System Research Rates
  - Remember to account for inflation in multiple year trials.
- Contact OSUP at (614) 947-3700 for professional fees, physician rates, professional consultation and/or Radiology/Wright Center Research services (Option 8)

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Enter Fixed Costs into Internal Budget

Protocol Budget Calendar

Contract No: 10000 **Protocol No:** XYZ **Department:** Research **Sponsor:** Pharma

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ITEMS & SERVICES											
Informed Consent			R								$0.00
Inclusion/Exclusion	R		R								$0.00
Chart Review	R		R								$0.00
Medical History	R		R								$0.00
Physicial Exam*	SOC & R		SOC		R	SOC	SOC	SOC			$0.00
Vital Signs	SOC & R		SOC	SOC	R	SOC	SOC	SOC			$0.00
Concominant Meds	R		R	R	R	R	R	R			$0.00
A/E Reporting	R			R	R	R	R	R			$0.00
Clinic Visit**	SOC & R				$110.00	SOC	SOC	SOC			$110.00
Pharmacy Fees	R		$25.00		$25.00	$25.00	$25.00	$25.00			$125.00
Chest X-Ray	SOC & R		SOC				SOC	SOC			$0.00
EKG	SOC & R		SOC	$25.00	$25.00	$25.00	$25.00	SOC			$100.00
Cardiac Angiogram***	SOC & R		SOC					$2,000.00			$2,000.00
Drug Accountability Logs	R		R		R	R	R	R			$0.00
CK-MB	SOC & R		SOC	SOC	$15.00	$15.00	$15.00	$15.00			$60.00
EKG Professional Read	SOC & R		SOC	$22.00	$22.00	$22.00	SOC	SOC			$66.00
Study Coordinator Time	R		R	R	R	R	R	R			$0.00
PI Time***	R		R	R		R	R	R			$0.00
Dry Ice	R		$10.00	$10.00			$10.00	$10.00			$40.00
Participant Stipends	R				$20.00	$20.00	$20.00	$20.00			$80.00
Participant Travel/Parking	R				$10.00	$10.00	$10.00	$10.00			$40.00
Central Lab Processing Time	R		R	R			R	R			$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
Sub-Total Per Participant Costs		$0.00	$35.00	$57.00	$227.00	$117.00	$105.00	$2,080.00	$0.00	$0.00	$2,621.00
Plus F&A Overhead Rate		$0.00	$9.10	$14.82	$59.02	$30.42	$27.30	$540.80	$0.00	$0.00	$681.46
TOTAL PER PARTICIPANT COSTS		**$0.00**	**$44.10**	**$71.82**	**$286.02**	**$147.42**	**$132.30**	**$2,620.80**	**$0.00**	**$0.00**	**$3,302.46**

Calendar Foot Notes: *Mth 1 PE is abbreviated. To be performed by Study RN, ** Mth 1 Level V, ***PI Performing angion. No Pro Fee, R-NB = Charges captured in other items

Current F&A rate	**26%**

Identify Personnel Costs

- The budget must include all personnel costs that will be required to conduct the study
  - Principal Investigator (PI): For overall conduct of study, study visits, etc.
  - Clinical Research Coordinator (CRC) or Nurse (CRN)
  - Regulatory Coordinator (RC)
  - Data Manager (DM)
  - Office Associate (OA)
  - Clinical Research Manager (CRM)
  - Biostats., Consultants, Sub-contractors

- Use the “Personnel Hourly Rate Calculator” template to help determine Hourly Rates for Staff (Part of Internal Budget Tool)

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Personnel Hourly Rate Calculator Template

(Worksheet is a Part of Internal Budget Template)

Step 1. Personnel Hourly Rate Calculator (Figure out Hourly Rate for Staff)

Category	Base Salary	Fringe Benefits (37%)	Total Salary	# Hours per year	Hourly Charge Back Rate
Clinical Research Nurse (CRN)		0	0	2080	0
CRC		0	0	2080	0
Regulatory Coordinator		0	0	2080	0
Data Manager		0	0	2080	0
Office Associate		0	0	2080	0
Clinical Research Manager (CRM)		0	0	2080	0
PI		0	0	2080	0

Customize for Your site

Step 2. Clinical Research Coordinator Standardized Hourly Charge Template

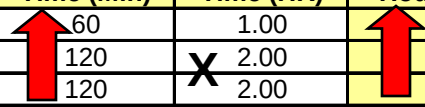
Procedure	Staff Responsible	Hourly Rate		Time (Min)	Time (Hr)		Cost per Procedure
Protocol Review (Simple)					0		0
Protocol Review (Complex)			X		0	=	0
Regulatory Document Preparation					0		0
Budget Preparation					0		0
CTA Negotiation					0		0
Informed Consent					0		0
Inclusion/Exclusion					0		0
Routine/OP Assessment					0		0
Medical History					0		0
Outpatient assesssment (Complex)					0		0
Patient Teaching					0		0
Vital Signs (routine)					0		0
Vital Signs (Complex)					0		0
Height/Weight					0		0
Specimen Collection (Simple)					0		0
Specimen Collection (Complex)					0		0
Specimen Processing (Simple)					0		0
Specimen Processing (Complex)					0		0
Medication Administration					0		0
Drug Accountability					0		0
Concominant Meds					0		0
A/E Assessment/Reporting					0		0

Add Staff Normally Responsible at your site, their Hourly Rate & the Average Time To Complete the Procedure

The Template Calculates the "Costs per Procedure"

Step 1. Personnel Hourly Rate Calculator (Figure out Hourly Rate for Staff)					
Category	**Base Salary**	**Fringe Benefits (37%)**	**Total Salary**	**# Hours per year**	**Hourly Charge Back Rate**
Clinical Research Nurse (CRN)	60000	22200	82200	2080	40
Clinical Research Coordinator (CRC)	46000	17020	63020	2080	30
Regulatory Coordinator (RC)	42000	15540	57540	2080	28
Data Manager (DM)	30000	11100	41100	2080	20
Office Associate (OA)	28000	10360	38360	2080	18
Clinical Research Manager (CRM)	69000	25530	94530	2080	45
PI	110000	40700	150700	2080	72

Step 2. Clinical Research Coordinator Standardized Hourly Charge Template					
Procedure	**Staff Responsible**	**Time (Min)**	**Time (HR)**	**Hourly Rate**	**Cost per Procedure**
Protocol Review (Simple)	CRM	60	1.00	45	45
Protocol Review (Complex)	CRM	120	2.00	45	90
Regulatory Document Preparation	RC	120	2.00	28	56
Budget Preparation	CRM	60	1.00	45	45
CTA Negotiation	CRM	60	1.00	45	45
Informed Consent	CRC	60	1.00	30	30
Inclusion/Exclusion	CRC	15	0.25	30	8
Routine/OP Assessment	CRC	15	0.25	30	8
Medical History	PI	15	0.25	72	18
Outpatient assesssment (Complex)	PI	30	0.50	72	36
Patient Teaching	CRC	15	0.25	30	8
Vital Signs (routine)	CRN	5	0.08	40	3
Vital Signs (Complex)	CRN	10	0.17	40	7
Height/Weight	CRC	5	0.08	30	3
Specimen Collection (Simple)	CRC	5	0.08	30	3
Specimen Collection (Complex)	CRC	10	0.17	30	5
Specimen Processing (Simple)	OA	10	0.17	18	3
Specimen Processing (Complex)	CRC	20	0.33	30	10
Medication Administration	CRN	5	0.08	40	3
Drug Accountability	CRC	5	0.08	30	3
Concominant Meds	CRN	10	0.17	40	7
A/E Assessment/Reporting	CRN	15	0.25	40	10
SAE Assessment/Reporting	CRN	30	0.50	40	20
Indirect Care (phone calls,etc.)	OA	5	0.08	18	2
Monitoring Visit Prep	CRC	20	0.33	30	10



Enter Personnel Costs per Procedure into Internal Budget Template

Protocol Budget Calendar

Contract No: 10000 **Protocol No:** XYZ **Department:** Research **Sponsor:** Pharma

Protocol Target Accrual: 10 **PI:** Investigator, Principal **Accrual to Date:** Assessment

Study Title: SAMPLE: Phase II, Double-Blind, Placebo-Controlled, Randomized, Multicenter Efficacy trial of XXX in participants with acute decompensated ischemic congenstive heart failure.

A. PER PARTICIPANT / PER ARM COSTS

	Schedule of Events										
	Standard of Care (SOC) Vs. Research (R)		Visit 1/ Day 0 = Hosp IP	Visit 2/ Day 1	Visit 3 / Mth 1	Visit 4 / Mth 3	Visit 5 / Mth 6	Visit 6 / Yr 1 = Final Visit			Row Totals
ITEMS & SERVICES											
Informed Consent			$30.00								$30.00
Inclusion/Exclusion	R		$8.00								$8.00
Chart Review	R		R-NB								$0.00
Medical History	R		$18.00								$18.00
Physicial Exam*	SOC & R		SOC		$36.00	SOC	SOC	SOC			$36.00
Vital Signs	SOC & R		SOC	SOC	$3.00	SOC	SOC	SOC			$3.00
Concominant Meds	R		$7.00	$7.00	$7.00	$7.00	$7.00	$7.00			$42.00
A/E Reporting	R			$10.00	$10.00	$10.00	$10.00	$10.00			$50.00
Clinic Visit**	SOC & R				$110.00	SOC	SOC	SOC			$110.00
Pharmacy Fees	R		$25.00		$25.00	$25.00	$25.00	$25.00			$125.00
Chest X-Ray	SOC & R		SOC				SOC	SOC			$0.00
EKG	SOC & R		SOC	$25.00	$25.00	$25.00	$25.00	SOC			$100.00
Cardiac Angiogram***	SOC & R		SOC					$2,000.00			$2,000.00
Drug Accountability Logs	R		$3.00		$3.00	$3.00	$3.00	$3.00			$15.00
CK-MB	SOC & R		SOC	SOC	$15.00	$15.00	$15.00	$15.00			$60.00
EKG Professional Read	SOC & R		SOC	$22.00	$22.00	$22.00	SOC	SOC			$66.00
Study Coordinator Time	R		$30.00	$30.00	$30.00	$30.00	$30.00	$30.00			$180.00
PI Time***	R		$72.00	$36.00		$36.00	$36.00	$72.00			$252.00
Dry Ice	R		$10.00	$10.00			$10.00	$10.00			$40.00
Participant Stipends	R				$20.00	$20.00	$20.00	$20.00			$80.00
Participant Travel/Parking	R				$10.00	$10.00	$10.00	$10.00			$40.00
Central Lab Processing Time	R		$10.00	$10.00			$10.00	$10.00			$40.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
											$0.00
Sub-Total Per Participant Costs		$0.00	$213.00	$150.00	$316.00	$203.00	$201.00	$2,212.00	$0.00	$0.00	$3,295.00
Plus F&A Overhead Rate		$0.00	$55.38	$39.00	$82.16	$52.78	$52.26	$575.12	$0.00	$0.00	$856.70
TOTAL PER PARTICIPANT COSTS		**$0.00**	**$268.38**	**$189.00**	**$398.16**	**$255.78**	**$253.26**	**$2,787.12**	**$0.00**	**$0.00**	**$4,151.70**

Some Items may be bundled into Staff Time

Calendar Foot Notes: *Mth 1 PE is abbreviated. To be performed by Study RN, ** Mth 1 Level V, ***PI Performing angion. No Pro Fee, R-NB = Charges captured in other items

Current F&A rate **26%**

Identify Start Up Costs

- Before a budget can be considered complete a site must factor in up front costs and potential misc. costs
  - Investigator Meeting Expenses, IRB Fees (Initial, annual, revisions), Administrative (Regulatory prep, Pre-Screening, Source Document Preparation, Training), Pharmacy fees, etc.

- Watch out for studies where large charges are incurred at the onset, may want to get a % of participant accrual costs up front

Enter Start Up Costs in Internal Budget Template

(Section B)

- Start Up Costs should be Non-Refundable and due upon work completed.
- If possible have sponsor pay central IRB fees directly (avoids overhead!)
- Sites generally charge $1,500 to 3,000 for Administrative Start Up Fees

B. START UP COSTS (Non-Refundable, Not Dependent upon Study, Dependent upon Work completed)			
	Base Rate	**F&A**	**Total**
Investigator Meeting Expenses		$0.00	$0.00
IRB Fees		$0.00	$0.00
Administrative Fee (for Regulatory Prep, Pre-Screening, Source Docs, Training)	$1,500.00	$390.00	$1,890.00
Investigational Drug Pharmacy	$500.00	$130.00	$630.00
Storage Costs	$125.00	$32.50	$157.50
Other		$0.00	$0.00
Sub-Total Start Up Costs	$2,125.00	$552.50	$2,677.50
Plus F&A Overhead Rate	$552.50		
TOTAL START UP COSTS	**$2,677.50**		
Start Up Footnotes: Investigator Meeting expenses paid for by the sponsor.			
*WIRB fees paid by sponsor directly.			

Don’t Forget Pass Through Items!

(Section C)

- Include the ability to Invoice for additional costs that may be incurred during the course of the study

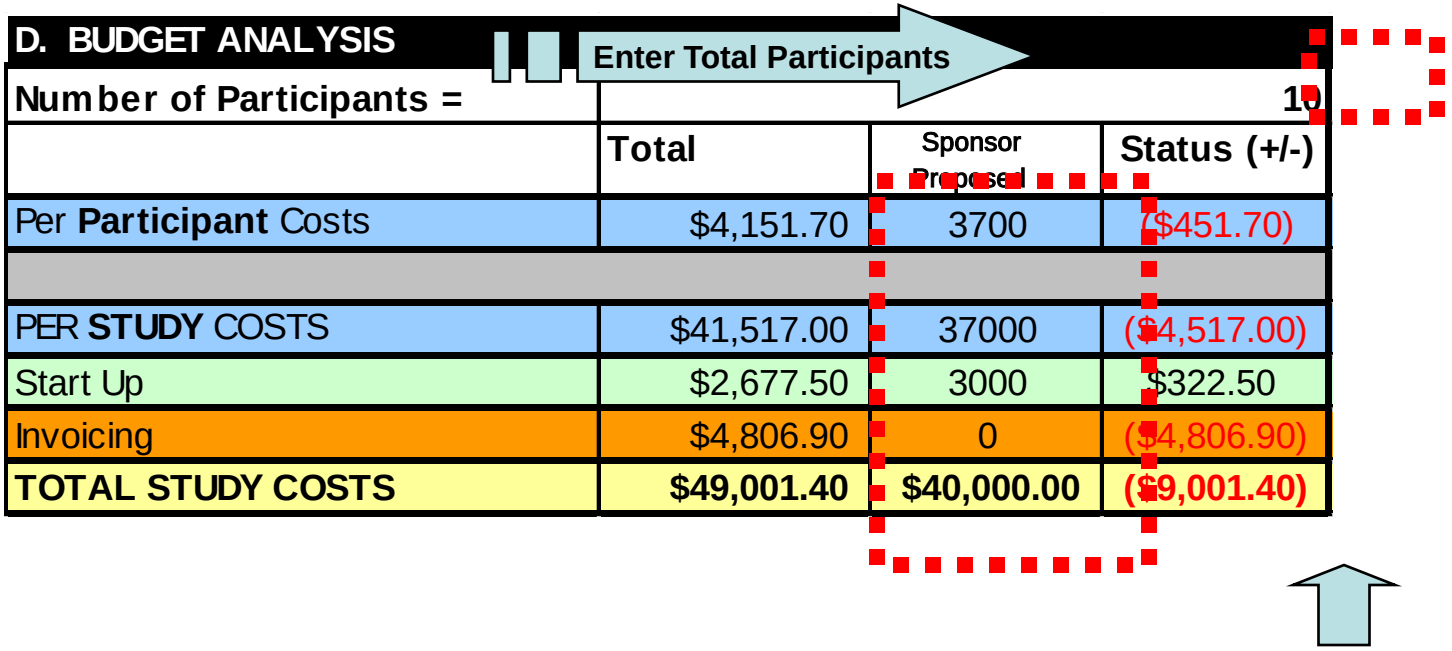
C. INVOICE / PASS THROUGH ITEMS: Include in Contract as payable upon invoice			
	Base Rate	F&A	Total
Travel	$1,500.00	$390.00	$1,890.00
Training	$500.00	$130.00	$630.00
Advertising	$500.00	$130.00	$630.00
Equipment		$0.00	$0.00
Consent Translation		$0.00	$0.00
Screen Failures	$250.00	$65.00	$315.00
Monitoring Visits	$125.00	$32.50	$157.50
Unscheduled Visits	$50.00	$13.00	$63.00
SAE's	$40.00	$10.40	$50.40
FDA or Sponsor Audits (per Day)	$500.00	$130.00	$630.00
IRB Continuing Review Fees	$250.00	$65.00	$315.00
Amendments	$50.00	$13.00	$63.00
Lost to Follow Up Tracking	$50.00	$13.00	$63.00
Other:		$0.00	$0.00
Sub-Total Invoicable Items	$3,815.00	$991.90	$4,806.90
Plus F&A Overhead Rate	$991.90		
TOTAL INVOICABLE COSTS	**$4,806.90**		

Compare Internal Budget to Sponsor Budget

(Section D)

- Enter the Number of Participants and the Sponsor Proposed payment for Per Participant, Start Up and Invoicing Costs.

D. BUDGET ANALYSIS			
Number of Participants =			10
	Total	**Sponsor Proposed**	**Status (+/-)**
Per **Participant** Costs	$4,151.70	3700	($451.70)
PER **STUDY** COSTS	$41,517.00	37000	($4,517.00)
Start Up	$2,677.50	3000	$322.50
Invoicing	$4,806.90	0	($4,806.90)
TOTAL STUDY COSTS	**$49,001.40**	**$40,000.00**	**($9,001.40)**



- The “Status” column should be a positive number.

Subsidizing

- If the sponsor payment does not cover costs the site should try to negotiate with the sponsor to at least cover costs.
- If the sponsor will not negotiate the site either has to turn down the study or find a way to subsidize it.
- Some studies may be worth subsidizing for scientific merit or for other reasons. Departments or other providers may sometimes agree to subsidize studies.
- The site needs to ensure they get approval from the appropriate person for subsidizing agreements. *Always get agreements in writing!*

Special Notes about Overhead

- Overhead (aka “indirects” or “F&A”) rates change periodically and are based upon type of study and type of service.
  - The link to the F&A rate agreement is http://rf.osu.edu/documents/FA_rate.pdf.
  - Info on F&A is at http://rf.osu.edu/development/facosts.cfm
- The College of Medicine 2008 approved rate is 26%
  - The overhead % is subject to change so speak to your SPO to verify the correct rate
- Remember to change the Excel formula in B43 in the Internal Budget Template when the overhead rate changes

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Negotiating Payment Terms

- Try to get sponsor to agree to a regular billing cycle for work completed rather than at specific participant milestones
- Don’t allow huge “holdbacks” on payment. If the sponsor requires holdbacks until final visits or the completion of data try to limit to less than 10%
- Consult the Research Billing Office about any contract provisions that limit what sponsors will pay for on procedures, injuries, etc.

Budgets & Billing Compliance

- Remember to factor in the Medicare rules for Clinical Research. See “Steps to Performing a Coverage Analysis” on the Research Billing Office Website
- Remember to keep the Budget, Contract, Consent, and Protocol in sync
  - The billing language must be consistent
- Ensure the budget and contract do not appear to contain items that are being billed to insurance as SOC

Monitor Budget and Payments

- Track your Study Costs
- Track Sponsor Payments
- Monitor what you have received, what bills are due, and what income is expected
  - Sponsors miss payments
  - Bills may be incorrect

Lessons Learned

- Update the templates and tools to incorporate the lessons learned from each study!

Contact

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