THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Knowledge that will change your world

The Business of Clinical Trials: Who Pays? Who Profits?

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  - Director of Clinical Research Operations, Rainbow Babies & Children's Hospital
- **Patrick Flume, MD**
  - Director or Cystic Fibrosis Center, Medical University of South Carolina

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

University Hospitals
Rainbow Babies & Children's Hospital

Objectives and Goals for Forum and Panel Discussion

- Understand and review the business of clinical trials
- Develop fair and appropriate budgets
- Understand both straightforward and under-recognized cost
- Developing a system for effective cost recovery
- Present tips and tools for successfully negotiating your budget

What do we mean by “The Business of Clinical Trials”

- **Managing the Program**
  - Hiring/Firing
  - Training and Certification, equipment maintenance, supplies
  - Developing a performance portfolio
- **Managing the Clinical Trials**
  - Performing feasibility assessments
  - Matching participation to interest
  - Recruitment
  - Recognizing and managing lack of success **(no activity does not equal no cost)**
- **Managing the Money**

First things First...Know Your Cost

- **Indirect Cost**
  - Money paid to the institution for basic infrastructure cost
- **Patient Care Cost**
  - Budgeted Items paid for services rendered (x-ray, labs, etc)
- **Personnel time**
  - PI, RC, Pharmacist, Administrative support to conduct the study visits
  - Poorly defined but often extensive, between patient demands on the team
- **Study Start-Up Cost**
- **Invoice Items**
- **Study Close out**
  - FDA audits, document storage

UAB Cystic Fibrosis Program Start-up Fees

Activity	PI Hours	RC Hours	Admin hours	Cost
Feasibility Questionnaire	2	2		$770
IRB Preparation	8	40		$5600
Budget/Contract Preparation	8	40	20	$7200
eCRF Training	1	4		$610
Site Initiation Visit	8	2		$1220
Source Document Development	2	16		$1940
CHRU FEE				$1500
Pharmacy Start Up Fee				$950
Subtotal start Up Cost				$19,790
Institutional Indirects (30%)				$5,937
Total				$25,727

Personnel Rates:
PI: $250/hr
RC: $90/hr
Admin: $80/hr
RA: $50/hr

Invoiceable Items

Know what your Invoiceables items are and plan ahead!!!

Procedures that **MIGHT** happen

Screen Fails

Pregnancy Test

Unscheduled Visits

Travel, Overnight Stays

Adverse Events

Creating Source Documentation

Dry Ice

Amendments, Renewal Fees

IND safety Reports

Document Retrieval (after close out)

FDA Audit

Procedures that **Will** Happen

Monitoring Visits

Archiving, Data Storage

Pharmacy Dispensing Fees

Close out Fees

Conference Calls

Develop your PI and RC time for these Invoiceables and be prepared!!!

Go into the Negotiation Prepared!

Use the Tools you have:

- Synopsis, study schedule, study design
- Subject Selection
  - Population, Inclusion/Exclusion
  - Study Drug
- Study procedures and guidelines
- Evaluations by visits
- Adverse event reporting
- Data Collection

Remember!!
A CRO/Sponsor will never offer the amount of compensation your deserve, only the amount you negotiate!!!

Negotiation Considerations

Study Visits

- Before the Visit
  - Prescreening, Recruitment, prep time,
- During the Visit
  - Study Activities, lab processing, shipping, dry Ice, complicated medical history review
- After the Visit
  - Data entry, queries
  - Processing Specimens/Shipping
  - Invoicing and reconciliation

For Example....

- ❑Identify the length of each visit
- ❑Identify the test that are billable
- ❑Are there both Tech/Professional costs associated with the test
- ❑Central Lab vs Local Lab
- ❑Review all footnotes, may find hidden cost
- ❑Determine personnel time

APPENDIX 1. SCHEDULE OF EVENTS

	Visit 1 Screening/ Baseline (Day1)	Visit 2 (Week 13)[a]	Visit 3 (Week 26)[a]	Visit 4 (Week 39)[a]	Visit 5 / Final Study Visit (Week 52)[a]	Early Withdrawal Visit
Review study/ obtain Informed Consent/HIPAA/Specimen Banking Consent/Consent to collect CFF Registry ID	X					
Assign unique screening number	X					
Record Demographics Data	X					
Record Medical History	X					
Record most recent respiratory microbiology culture	X				X	X
Concomitant Medications	X	X	X	X	X	X
Confirm Eligibility	X					
Adverse Event		X	X	X	X	X
Administer study instruments[b]:						
1.CFRSD	X	X	X	X	X	X
2.CFQ-R	X	X	X	X	X	X
3.TAQ-CF	X	X	X	X	X	X
4.HADS	X	X	X	X	X	X
5.MOS-SSS	X	X	X	X	X	X
6.Global Assessment of Protocol Burden					X	X
Complete Physical Exam	X				X	X
Abbreviated Physical Exam		X	X	X		
Vital signs, height, weight	X	X	X	X	X	X
Oximetry	X	X	X	X	X	X
Spirometry	X	X	X	X	X	X
Blood for Repository[d]	X					
Randomization	X					
Early Intervention group training	X					
Review standard approach to exacerbation management	X					
Pulmonary Signs and Symptoms Evaluation		X	X	X	X	X

[a] ±7 days
[b] Subject questionnaires should be administered at the start of each study visit.
[c] For subjects randomized to the Early Intervention arm, training includes use of AM2 monitor for both spirometry and CFRSD, demonstration of data transmission, and providing subjects with AM2 monitor and data transmission equipment. Baseline for AM2 monitor for both spirometry and CFRSD will be performed at this study visit.
[d] Only if specific consent has been given. For subjects whose baseline visit has occurred prior to the date of IRB Approval of Protocol Amendment 1, a baseline specimen for the clinical biorepository can be collected at a subsequent visit provided the subject is not exacerbating (is in a clinically stable state).

For Example....

Study Procedures with Time Costs

Please use the Schedule of Events below to estimate the staff time to complete the visit.

Procedures that are typically charged with a set procedure cost (and not based on time) are not included in this list and the procedure cost should be entered on the Site Standard Costs tab.

eICE-ID-10	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Acute Visit w/blood draw	Acute Visit w/out blood draw	Acute FU Visit
Pre-screening (Medical Record Review)	X							
Informed consent and assent	X							
Demographics/CF Diagnosis	X							
Medical History	X							
Signs and Symptoms (Baseline and AEs)	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Concomitant Medications Review	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Administration of CFRSD	X	X	X	X	X	X	X	X
Administration of CFQ-R,TAQ,HADS,MOS	X	X	X	X	X			
Administration of Treatment Burden					X			
Physical Exam (PI)	SOC				SOC			
Abbreviated Physical Exam		SOC	SOC	SOC		SOC	SOC	SOC
Vital Signs	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Weight and Height	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Oximetry Randomize	X X	X	X	X	X	X	X	X
Early intervention training	[X]							
Review exacerbation management	X							
Visit Prep and Follow-up	X	X	X	X	X	X	X	X

Key: Only procedures done for research purposes will be reimbursed.

X Procedure should be included in the estimate for staff time as this procedure is being performed for research only.

SOC Procedure is performed as part of standard of care. Do not include as part of estimate for staff time.

[X] Only need to perform for half of subjects

TIPS:

- ❑Use this as a worksheet!!!!
- ❑Allows you to identify SOC
- ❑You may find things in the protocol not listed on the schedule of events
- ❑Every visit should include PI time
- ❑Include RC prep time
- ❑Include data entry and query resolution
- ❑Don’t shortchange yourself

Now your Ready to Negotiate!!

“Let us Never negotiate our of fear, but let us never fear to negotiate”
-John F. Kennedy

How do we come to an agreement?

Negotiation process steps

1. Follow the same process for every study
2. You must know how far you can lower your charges without losing money
3. You should understand the concept of fair market value
4. Establish a site specific checklist for all aspects of the process
5. Know when to walk away, even if temporarily

Fair Market Value

What is Fair Market Value?

- Average cost/charge of a procedure across all markets
- May be based on previously negotiated amounts from other trials at your site or an aggregate of other sites
- A sponsor may determine the lowest negotiated amount for an item and apply it across all sites.
- Fair market value must be addressed per site (i.e. past performance) and per market
  - As well as per disease
  - And in response to protocol specifications (in patient vs outpatient)

Billing and Reconciliation

You Negotiated the Contract

and

You Did the Work

so

COLLECT THE MONEY

Business of Clinical Trials Trivia

What is the average percentage of the Budget that research sites do not collect due to lack of invoicing???

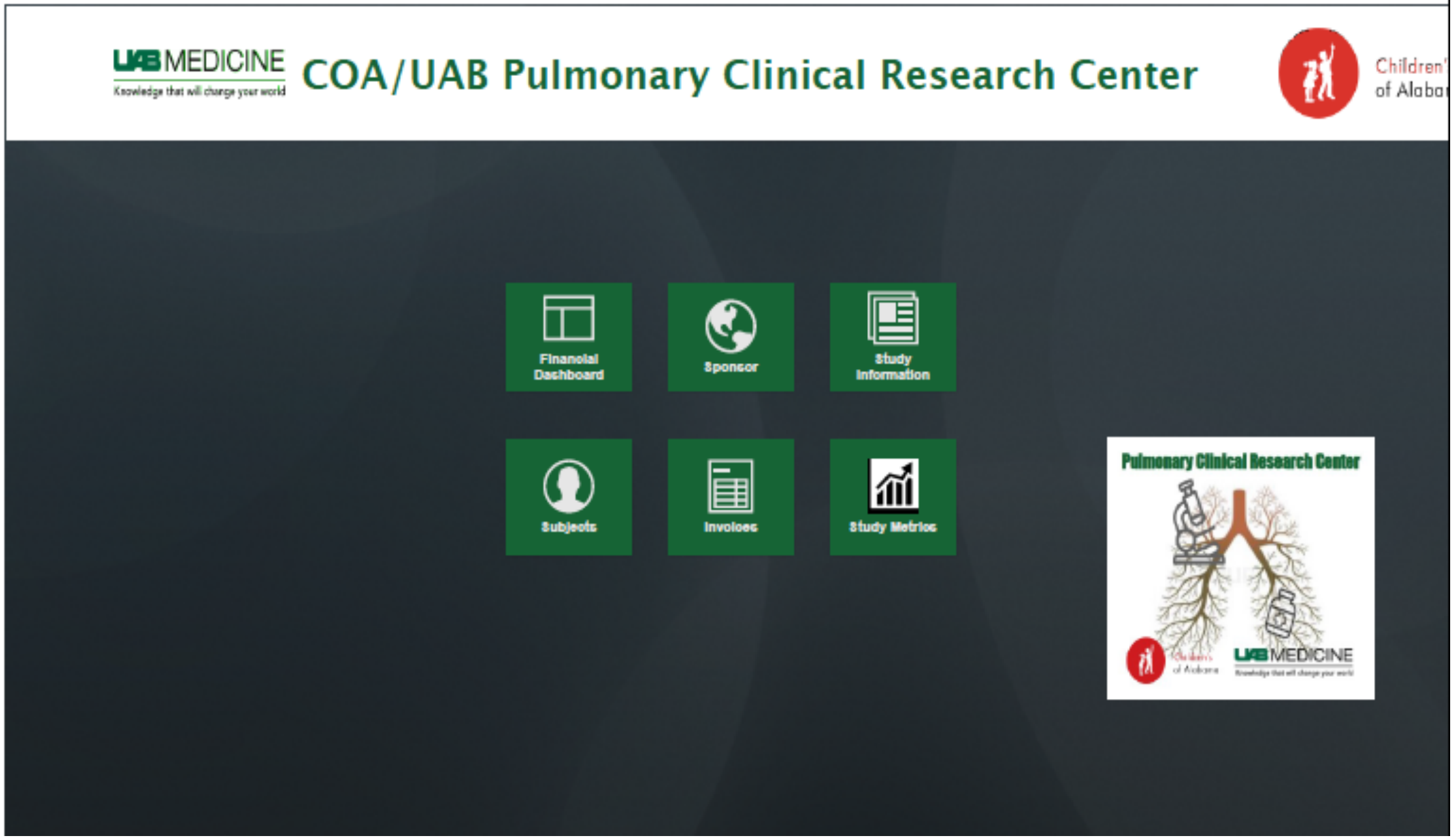
26%

Source: Quintiles, SCRS (2016), Tufts CSDD

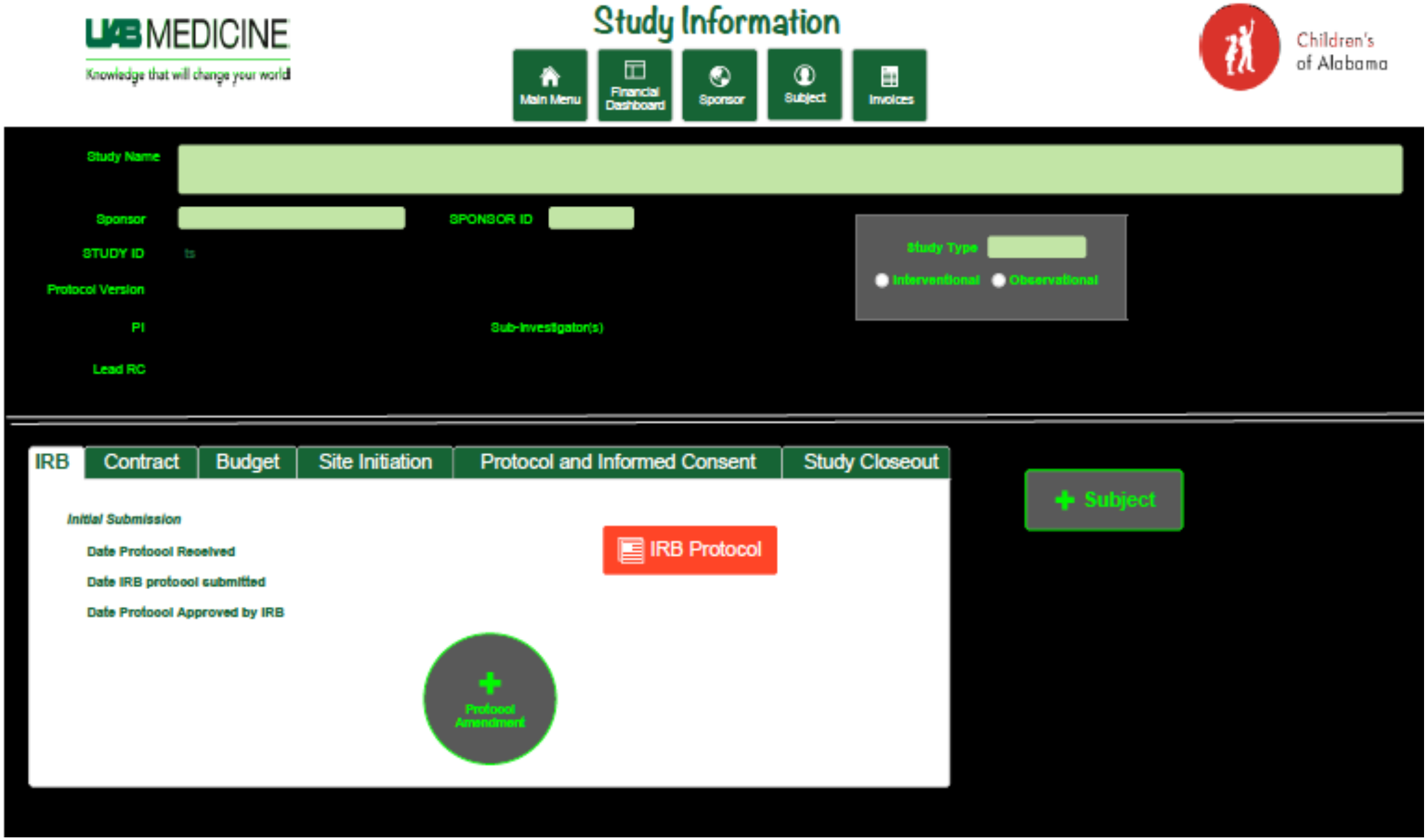
Billing and Reconciliation

While we wait for Oncore….

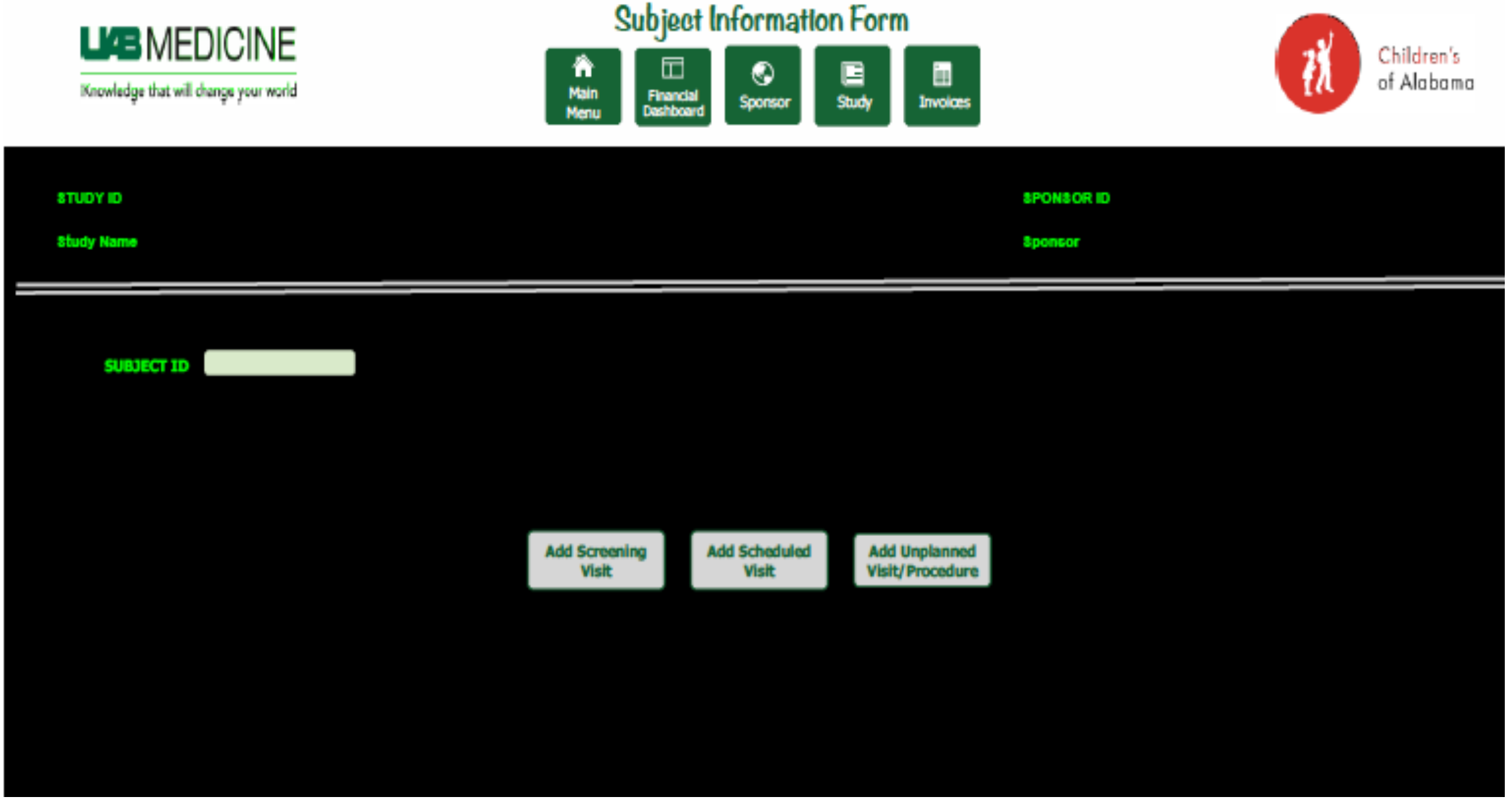
- Develop a system for tracking all charges and events
- Submit invoices for all of these items according to the time schedule outlined in the contract
- Reconcile the payments with invoices on a periodic basis
- Do not close the grant until you are assured you have received all payments



Filemaker, billing program designed by Isabel Virella-Lowell, MD



Filemaker, billing program designed by Isabel Virella-Lowell, MD



Filemaker, billing program designed by Isabel Virella-Lowell, MD

Wednesday, June 28, 2017 at 12:20:06 PM Eastern Daylight Time

Subject: Invoice #014 | COA/UAB PULMONARY CLINICAL RESEARCH CENTER
From: Isabel Lowell
To: smith, john
CC: hhathorne@peds.uab.edu , tirby@peds.uab.edu, thyrzajohnson@uabmc.edu, miriammiles@uabmc.edu
Attachments: Invoice 014.pdf

Please review attached invoice and remit payment by due date.

Thank you,

UAB/COA Pulmonary Clinical Research Center

Pulmonary Clinical Research Center

INVOICE

COA/UAB PULMONARY CLINICAL RESEARCH CENTER

Invoice #: 014

DATE: 6/28/2017

TS
Sponsor ID: 1010

Attn: Miriam Miles
UAB
1600 7th Avenue South, LHT 752H
Birmingham, AL 35233

Payment in full is due by 7/28/2017

BILL TO:
TS
123 research drive
Birmingham, AL 35233
USA

ITEM	QTY	UNIT PRICE	AMOUNT
Budget Preparation	1	8,240	$8,240.00
IRB Preparation and Submission	1	4,640	$4,640.00
Lab Set Up Fee	1	1,300	$1,300.00
Site Initiation Visit	1	1,140	$1,140.00

Subtotal **$15320.00**

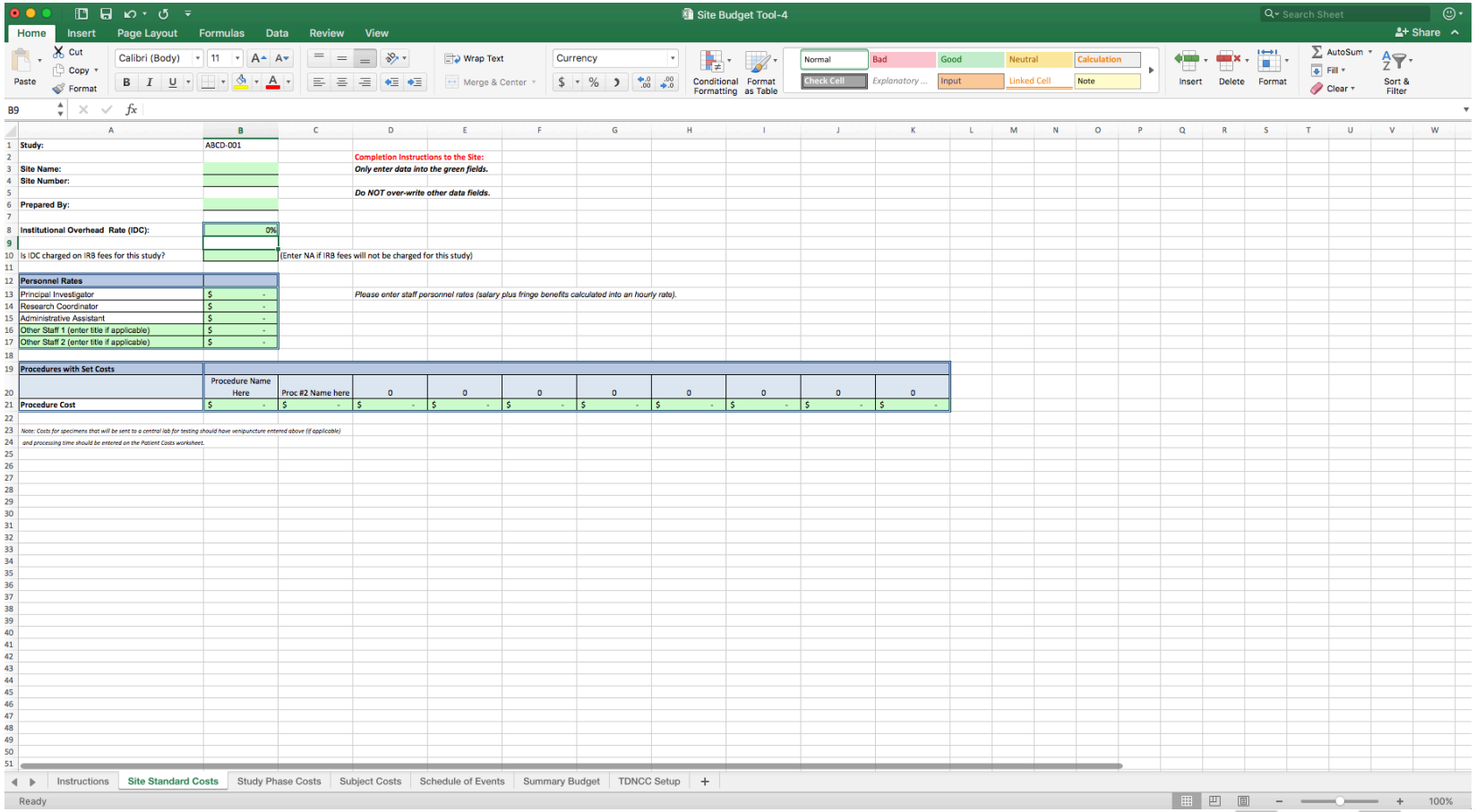
Indirect Costs **$4596.00**

TOTAL **$19916.00**

Filemaker, billing program designed by Isabel Virella-Lowell, MD

Example Budget Tool

Site Standard Cost



Site Budget Tool-4

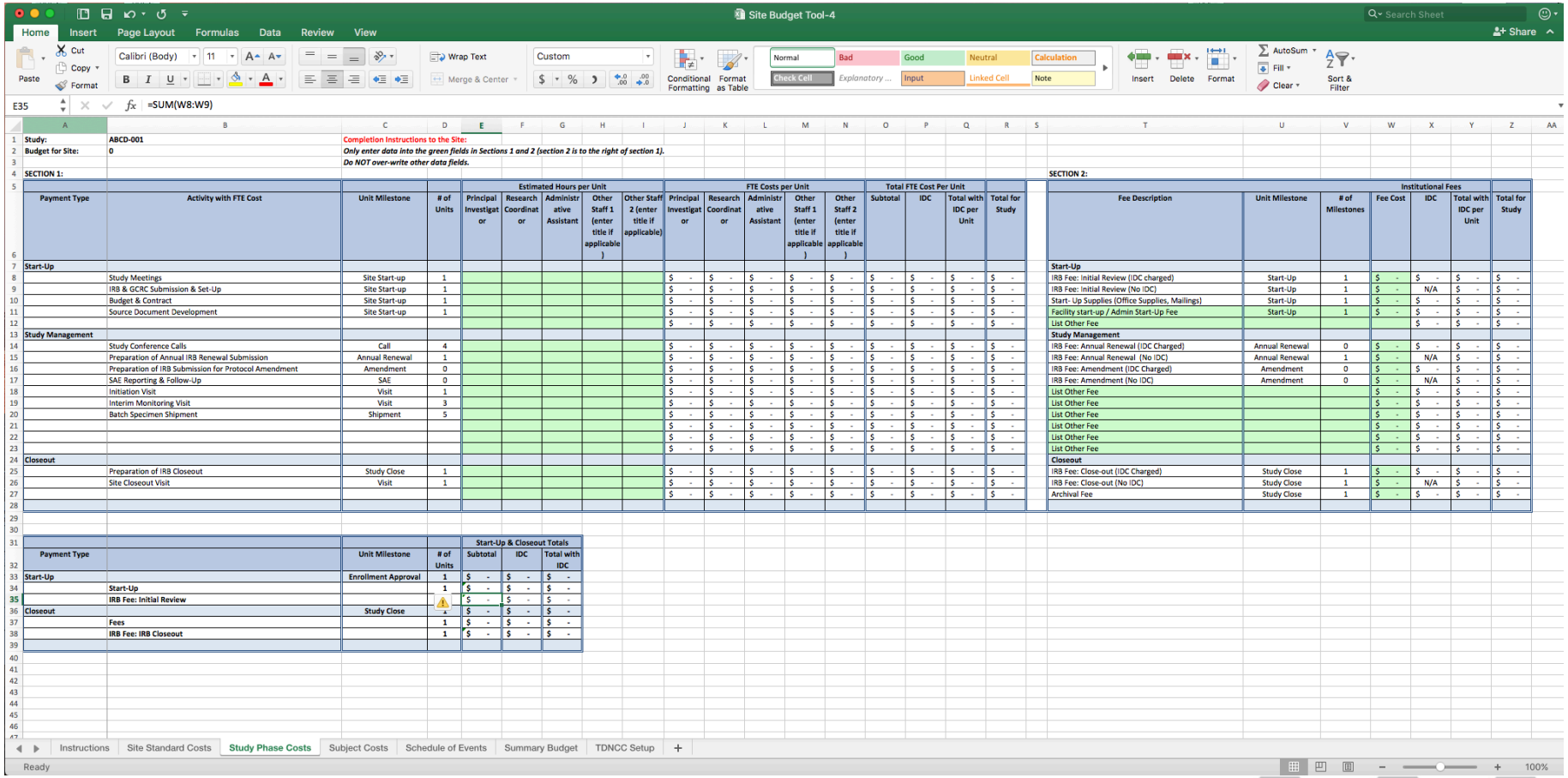
	A	B	C	D	E	F	G	H	I	J	K
1	**Study:**	ABCD-001									
2				**Completion Instructions to the Site:**							
3	**Site Name:**			***Only enter data into the green fields.***							
4	**Site Number:**										
5				***Do NOT over-write other data fields.***							
6	**Prepared By:**										
7											
8	**Institutional Overhead Rate (IDC):**	0%									
9											
10	Is IDC charged on IRB fees for this study?		(Enter NA if IRB fees will not be charged for this study)								
11											
12	**Personnel Rates**										
13	Principal Investigator	$ -		*Please enter staff personnel rates (salary plus fringe benefits calculated into an hourly rate).*							
14	Research Coordinator	$ -									
15	Administrative Assistant	$ -									
16	Other Staff 1 (enter title if applicable)	$ -									
17	Other Staff 2 (enter title if applicable)	$ -									
18											
19	**Procedures with Set Costs**										
20		Procedure Name Here	Proc #2 Name here	0	0	0	0	0	0	0	0
21	**Procedure Cost**	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
22											
23	*Note: Costs for specimens that will be sent to a central lab for testing should have venipuncture entered above (if applicable)*										
24	*and processing time should be entered on the Patient Costs worksheet.*										

Instructions | Site Standard Costs | Study Phase Costs | Subject Costs | Schedule of Events | Summary Budget | TDNCC Setup

Ready

Example Budget Tool

Study Phase Cost



Site Budget Tool-4

Study:	ABCD-001	Completion Instructions to the Site:
Budget for Site:	0	*Only enter data into the green fields in Sections 1 and 2 (section 2 is to the right of section 1).*
		Do NOT over-write other data fields.
SECTION 1:		

Payment Type	Activity with FTE Cost	Unit Milestone	# of Units	Estimated Hours per Unit: Principal Investigator	Research Coordinator	Administrative Assistant	Other Staff 1 (enter title if applicable)	Other Staff 2 (enter title if applicable)	FTE Costs per Unit: Principal Investigator	Research Coordinator	Administrative Assistant	Other Staff 1 (enter title if applicable)	Other Staff 2 (enter title if applicable)	Total FTE Cost Per Unit: Subtotal	IDC	Total with IDC per Unit	Total for Study
Start-Up																	
	Study Meetings	Site Start-up	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	IRB & GCRC Submission & Set-Up	Site Start-up	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Budget & Contract	Site Start-up	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Source Document Development	Site Start-up	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
									$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Study Management																	
	Study Conference Calls	Call	4						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Preparation of Annual IRB Renewal Submission	Annual Renewal	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Preparation of IRB Submission for Protocol Amendment	Amendment	0						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	SAE Reporting & Follow-Up	SAE	0						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Initiation Visit	Visit	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Interim Monitoring Visit	Visit	3						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Batch Specimen Shipment	Shipment	5						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
									$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
									$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
									$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Closeout																	
	Preparation of IRB Closeout	Study Close	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	Site Closeout Visit	Visit	1						$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
									$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

SECTION 2:

Fee Description	Unit Milestone	# of Milestones	Institutional Fees: Fee Cost	IDC	Total with IDC per Unit	Total for Study
Start-Up						
IRB Fee: Initial Review (IDC charged)	Start-Up	1	$ -	$ -	$ -	$ -
IRB Fee: Initial Review (No IDC)	Start-Up	1	$ -	N/A	$ -	$ -
Start- Up Supplies (Office Supplies, Mailings)	Start-Up	1	$ -	$ -	$ -	$ -
Facility start-up / Admin Start-Up Fee	Start-Up	1	$ -	$ -	$ -	$ -
List Other Fee				$ -	$ -	$ -
Study Management						
IRB Fee: Annual Renewal (IDC Charged)	Annual Renewal	0	$ -	$ -	$ -	$ -
IRB Fee: Annual Renewal (No IDC)	Annual Renewal	1	$ -	N/A	$ -	$ -
IRB Fee: Amendment (IDC Charged)	Amendment	0	$ -	$ -	$ -	$ -
IRB Fee: Amendment (No IDC)	Amendment	0	$ -	N/A	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
List Other Fee			$ -	$ -	$ -	$ -
Closeout						
IRB Fee: Close-out (IDC Charged)	Study Close	1	$ -	$ -	$ -	$ -
IRB Fee: Close-out (No IDC)	Study Close	1	$ -	N/A	$ -	$ -
Archival Fee	Study Close	1	$ -	$ -	$ -	$ -

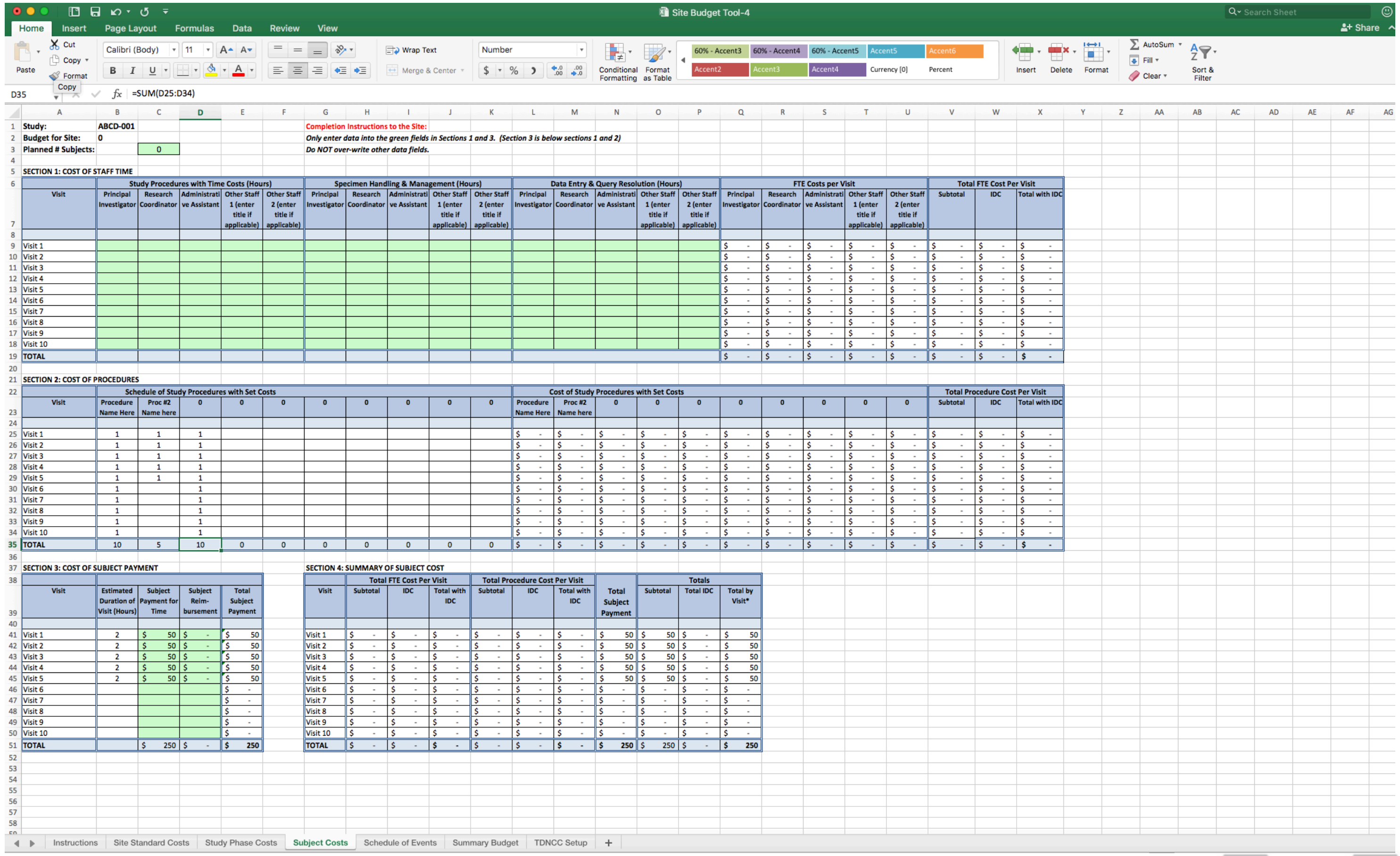
Payment Type		Unit Milestone	# of Units	Start-Up & Closeout Totals: Subtotal	IDC	Total with IDC
Start-Up		Enrollment Approval	1	$ -	$ -	$ -
	Start-Up		1	$ -	$ -	$ -
	IRB Fee: Initial Review			$ -	$ -	$ -
Closeout		Study Close		$ -	$ -	$ -
	Fees		1	$ -	$ -	$ -
	IRB Fee: IRB Closeout		1	$ -	$ -	$ -

Instructions | Site Standard Costs | Study Phase Costs | Subject Costs | Schedule of Events | Summary Budget | TDNCC Setup

Ready

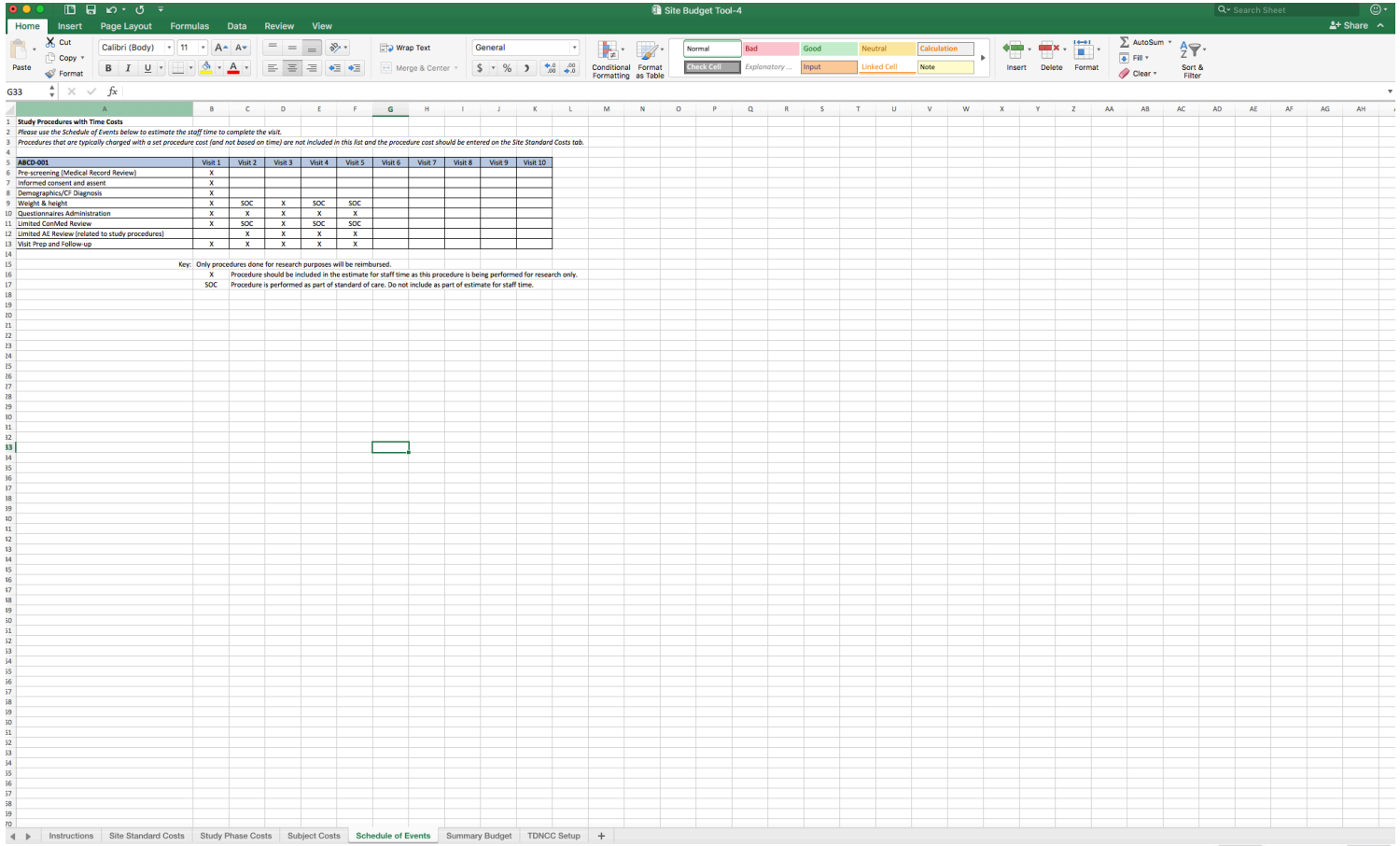
Example Budget Tool

Subject Cost



Example Budget Tool

Schedule of Events



Site Budget Tool-4

Study Procedures with Time Costs

Please use the Schedule of Events below to estimate the staff time to complete the visit.

Procedures that are typically charged with a set procedure cost (and not based on time) are not included in this list and the procedure cost should be entered on the Site Standard Costs tab.

ABCD-001	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10
Pre-screening (Medical Record Review)	X									
Informed consent and assent	X									
Demographics/CF Diagnosis	X									
Weight & height	X	SOC	X	SOC	SOC					
Questionnaires Administration	X	X	X	X	X					
Limited ConMed Review	X	SOC	X	SOC	SOC					
Limited AE Review (related to study procedures)		X	X	X	X					
Visit Prep and Follow-up	X	X	X	X	X					

Key: Only procedures done for research purposes will be reimbursed.

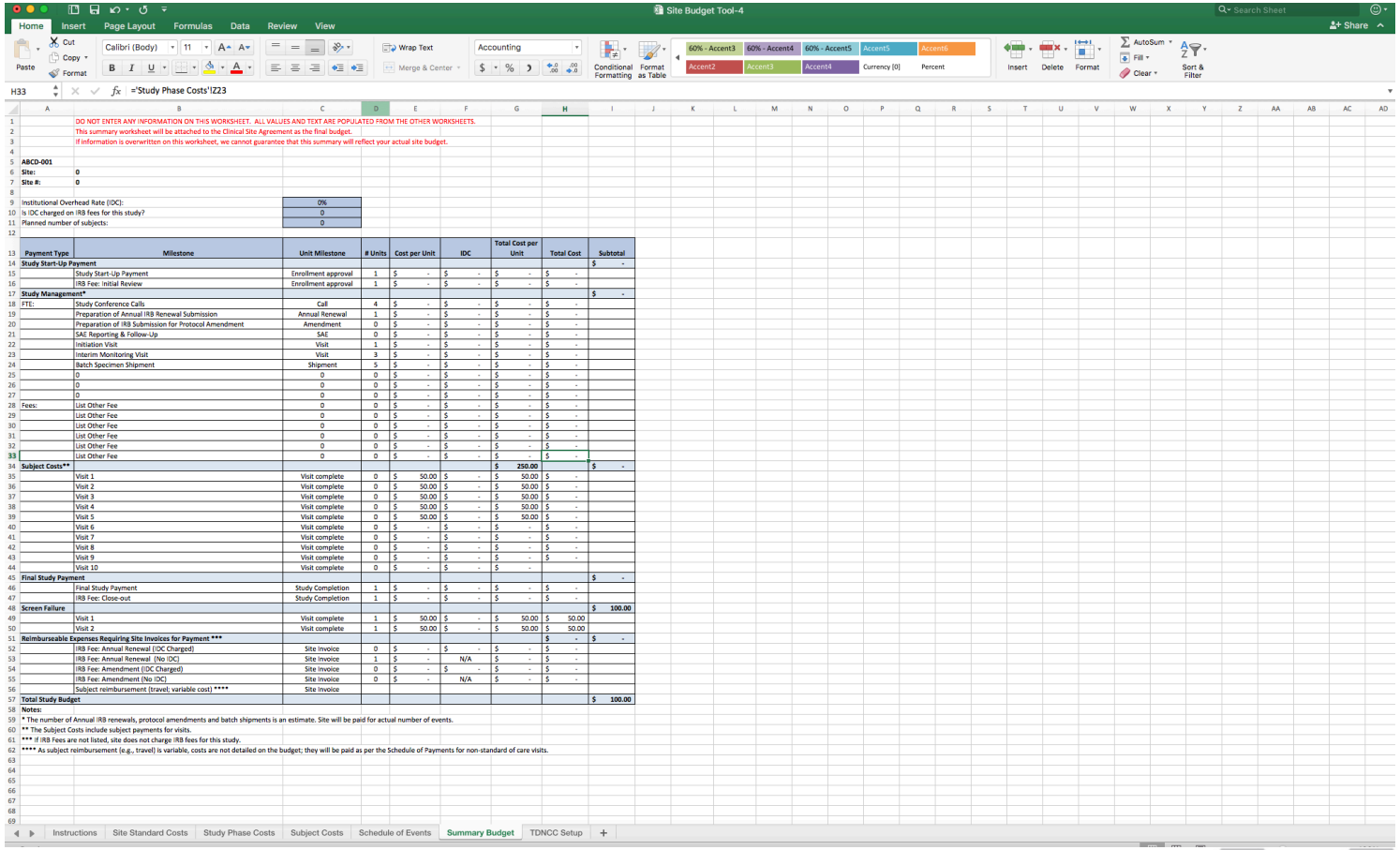
X — Procedure should be included in the estimate for staff time as this procedure is being performed for research only.

SOC — Procedure is performed as part of standard of care. Do not include as part of estimate for staff time.

Instructions | Site Standard Costs | Study Phase Costs | Subject Costs | Schedule of Events | Summary Budget | TDNCC Setup

Example Budget Tool

Summary Budget



DO NOT ENTER ANY INFORMATION ON THIS WORKSHEET. ALL VALUES AND TEXT ARE POPULATED FROM THE OTHER WORKSHEETS.
This summary worksheet will be attached to the Clinical Site Agreement as the final budget.
If information is overwritten on this worksheet, we cannot guarantee that this summary will reflect your actual site budget.

ABCD-001
Site: 0
Site #: 0

Institutional Overhead Rate (IDC):	0%
Is IDC charged on IRB fees for this study?	0
Planned number of subjects:	0

Payment Type	Milestone	Unit Milestone	# Units	Cost per Unit	IDC	Total Cost per Unit	Total Cost	Subtotal
Study Start-Up Payment								$ -
	Study Start-Up Payment	Enrollment approval	1	$ -	$ -	$ -	$ -	
	IRB Fee: Initial Review	Enrollment approval	1	$ -	$ -	$ -	$ -	
Study Management*								$ -
FTE:	Study Conference Calls	Call	4	$ -	$ -	$ -	$ -	
	Preparation of Annual IRB Renewal Submission	Annual Renewal	1	$ -	$ -	$ -	$ -	
	Preparation of IRB Submission for Protocol Amendment	Amendment	0	$ -	$ -	$ -	$ -	
	SAE Reporting & Follow-Up	SAE	0	$ -	$ -	$ -	$ -	
	Initiation Visit	Visit	1	$ -	$ -	$ -	$ -	
	Interim Monitoring Visit	Visit	3	$ -	$ -	$ -	$ -	
	Batch Specimen Shipment	Shipment	5	$ -	$ -	$ -	$ -	
	0	0	0	$ -	$ -	$ -	$ -	
	0	0	0	$ -	$ -	$ -	$ -	
	0	0	0	$ -	$ -	$ -	$ -	
Fees:	List Other Fee	0	0	$ -	$ -	$ -	$ -	
	List Other Fee	0	0	$ -	$ -	$ -	$ -	
	List Other Fee	0	0	$ -	$ -	$ -	$ -	
	List Other Fee	0	0	$ -	$ -	$ -	$ -	
	List Other Fee	0	0	$ -	$ -	$ -	$ -	
	List Other Fee	0	0	$ -	$ -	$ -	$ -	
Subject Costs**						$ 250.00		$ -
	Visit 1	Visit complete	0	$ 50.00	$ -	$ 50.00	$ -	
	Visit 2	Visit complete	0	$ 50.00	$ -	$ 50.00	$ -	
	Visit 3	Visit complete	0	$ 50.00	$ -	$ 50.00	$ -	
	Visit 4	Visit complete	0	$ 50.00	$ -	$ 50.00	$ -	
	Visit 5	Visit complete	0	$ 50.00	$ -	$ 50.00	$ -	
	Visit 6	Visit complete	0	$ -	$ -	$ -	$ -	
	Visit 7	Visit complete	0	$ -	$ -	$ -	$ -	
	Visit 8	Visit complete	0	$ -	$ -	$ -	$ -	
	Visit 9	Visit complete	0	$ -	$ -	$ -	$ -	
	Visit 10	Visit complete	0	$ -	$ -	$ -		
Final Study Payment								$ -
	Final Study Payment	Study Completion	1	$ -	$ -	$ -	$ -	
	IRB Fee: Close-out	Study Completion	1	$ -	$ -	$ -	$ -	
Screen Failure								$ 100.00
	Visit 1	Visit complete	1	$ 50.00	$ -	$ 50.00	$ 50.00	
	Visit 2	Visit complete	1	$ 50.00	$ -	$ 50.00	$ 50.00	
Reimburseable Expenses Requiring Site Invoices for Payment ***							$ -	$ -
	IRB Fee: Annual Renewal (IDC Charged)	Site Invoice	0	$ -	$ -	$ -	$ -	
	IRB Fee: Annual Renewal (No IDC)	Site Invoice	1	$ -	N/A	$ -	$ -	
	IRB Fee: Amendment (IDC Charged)	Site Invoice	0	$ -	$ -	$ -	$ -	
	IRB Fee: Amendment (No IDC)	Site Invoice	0	$ -	N/A	$ -	$ -	
	Subject reimbursement (travel; variable cost) ****	Site Invoice						
Total Study Budget								$ 100.00

Notes:
* The number of Annual IRB renewals, protocol amendments and batch shipments is an estimate. Site will be paid for actual number of events.
** The Subject Costs include subject payments for visits.
*** If IRB Fees are not listed, site does not charge IRB fees for this study.
**** As subject reimbursement (e.g., travel) is variable, costs are not detailed on the budget; they will be paid as per the Schedule of Payments for non-standard of care visits.

Start-Up Timeline Tool

Site Start-Up Timeline Template	
Protocol Number:	**Protocol Title:**

The table below includes tasks associated with study start up, typical turn-around time and target dates for completion. The table also identifies the personnel responsible for completing the task. This tool can be customized for your site specific requirements.

Task	Personnel	Time Required	Target Start Date	Target Complete Date	Actual Completed Date
Review budget	PI/RC/Business Manager	3 – 5 hours			
IRB prep/review by sponsor	PI or RC	Prep (10 hours) Sponsor (2-5 days)			
IRB submission	RC	2-3 hours			
IRB review	By Committee	Depends on schedule			
Peds IRB review	By Committee	Ad hoc 2 weeks			
PRC-GCRC review	By Committee	3 weeks to get on schedule			
PRC-GCRC preparation	RC	2-3 hours			
Contract review/ negotiations	By Legal	4-6 weeks			
Obtain IRB approval	PI/RC	Concurrent w/contract			
Finalize contract	PI/RC	Concurrent w/IRB approval			
Investigator Meeting	PI/RC	1-2 days			
Site Initiation Visit	PI/RC	1 day			
Enroll 1st Subject	PI/RC	1 day			

Panel Discussion

- **Steven Rowe, MD, MSPH**
  Director, Gregory Fleming James Cystic Fibrosis Research Center
  Co-Director, CCTS Children's Health Research Unit
- **Mansoor Saleh, MD**
  Medical Director, UAB Clinical Trials Administration Office
  Director, CCTS/CCC Phase I Clinical Trial Unit
- **Mark Dransfield, MD**
  Department of Medicine Professor, Division of Pulmonary, Allergy, and Critical Care, Director UAB Lung Health Center

Questions?

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