

Clinical Research Budgets

Next Steps

Rebecca Mercado, MSHE, CHES
University of Florida

Jessica Howard, MA, MPH
Boston University/Boston Medical Center

Disclosures & Disclaimers

- No disclosures
- Disclaimers & Finance Experience
 - Jessica: 17+ years of Clinical Research experience
 - Rebecca: 10 years in business and finance, 10 years of Clinical Research experience
- All examples are inspired by real scenarios. Rates or pricing have been altered. Any direct comparison to a specific study or project is not intended.

Objectives

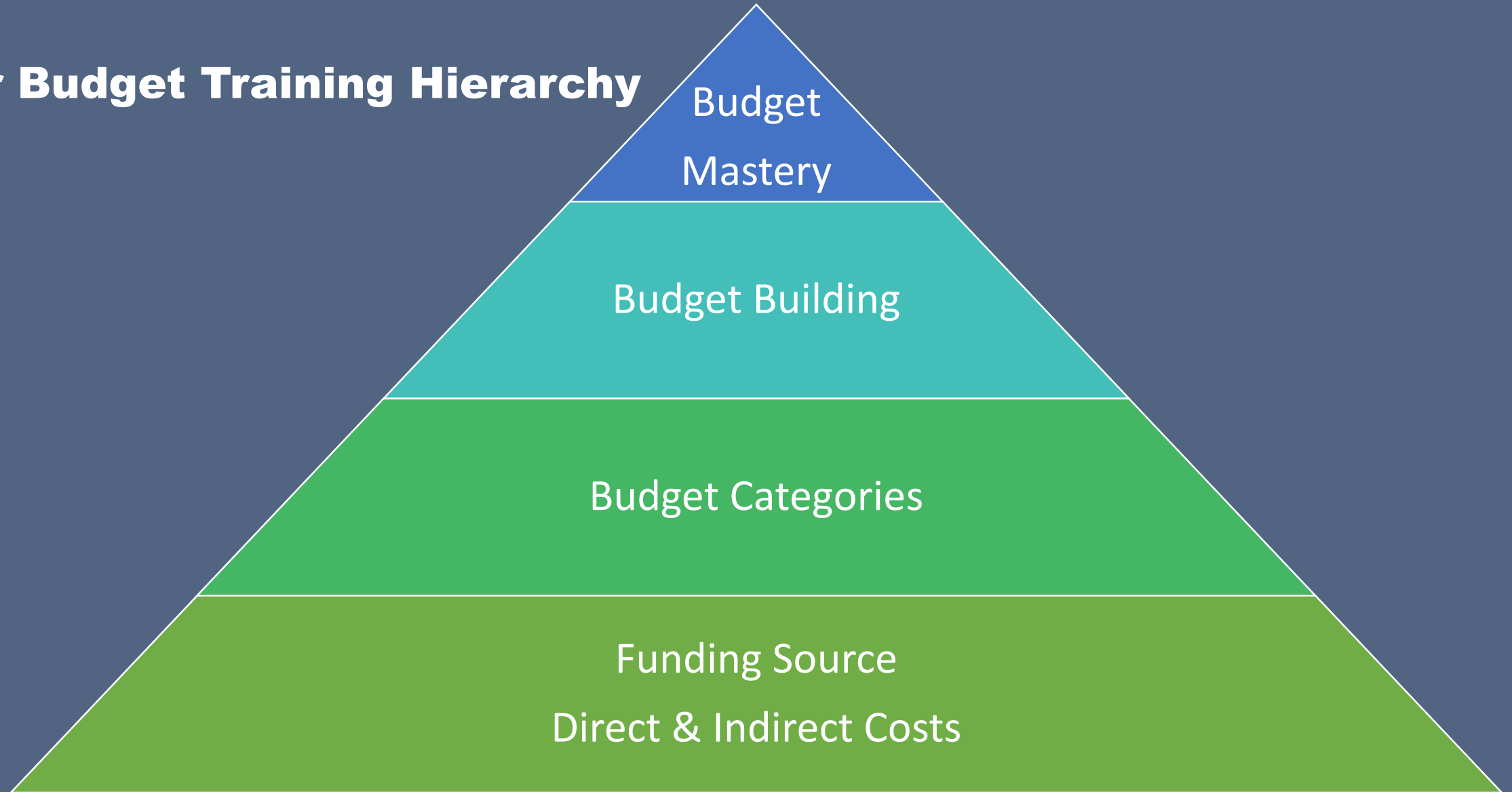
1. Review budget categories and terms
2. Assemble important budget tools
3. Apply your knowledge to execute a budget draft
4. Recognize common budgeting pitfalls

Interactive Session

- Zoom Whiteboard Stamping
 - Go to the top of your Zoom screen & hover
 - “View options” - Drop down and click on “Annotate”
 - Click “Stamp” (4th from the left on menu bar)
 - Use a star or heart stamp to note your choice!
 - (if no stamp option appears just choose “pen” and circle your choice)
- Discussion Group
- Chat Feature

A Quick Review

Our Budget Training Hierarchy



Pick Your Adventure: Funder & Cost Categories

- **Funding Sources**: Federal vs. Foundation vs. Industry Sponsored
 - Investigator Initiated vs. Industry Initiated
- **Direct Costs**: Costs that can be directly assigned to a particular project, are *necessary, reasonable* and *ALLOWABLE*.
- **Indirect Costs** (= Overhead = Facilities & Administration (F&A)): Costs that represent the expenses of doing business that cannot be easily assigned to a particular project.

Direct & Indirect Costs Examples

DIRECT Costs

- Salary
- Fringe benefits
- Conference fees
- Contracted services
- Participant bloodwork
- Subcontracts/Subawards

INDIRECT Costs

- General office supplies & equipment
- Rent
- Utilities
- Administrative & financial management

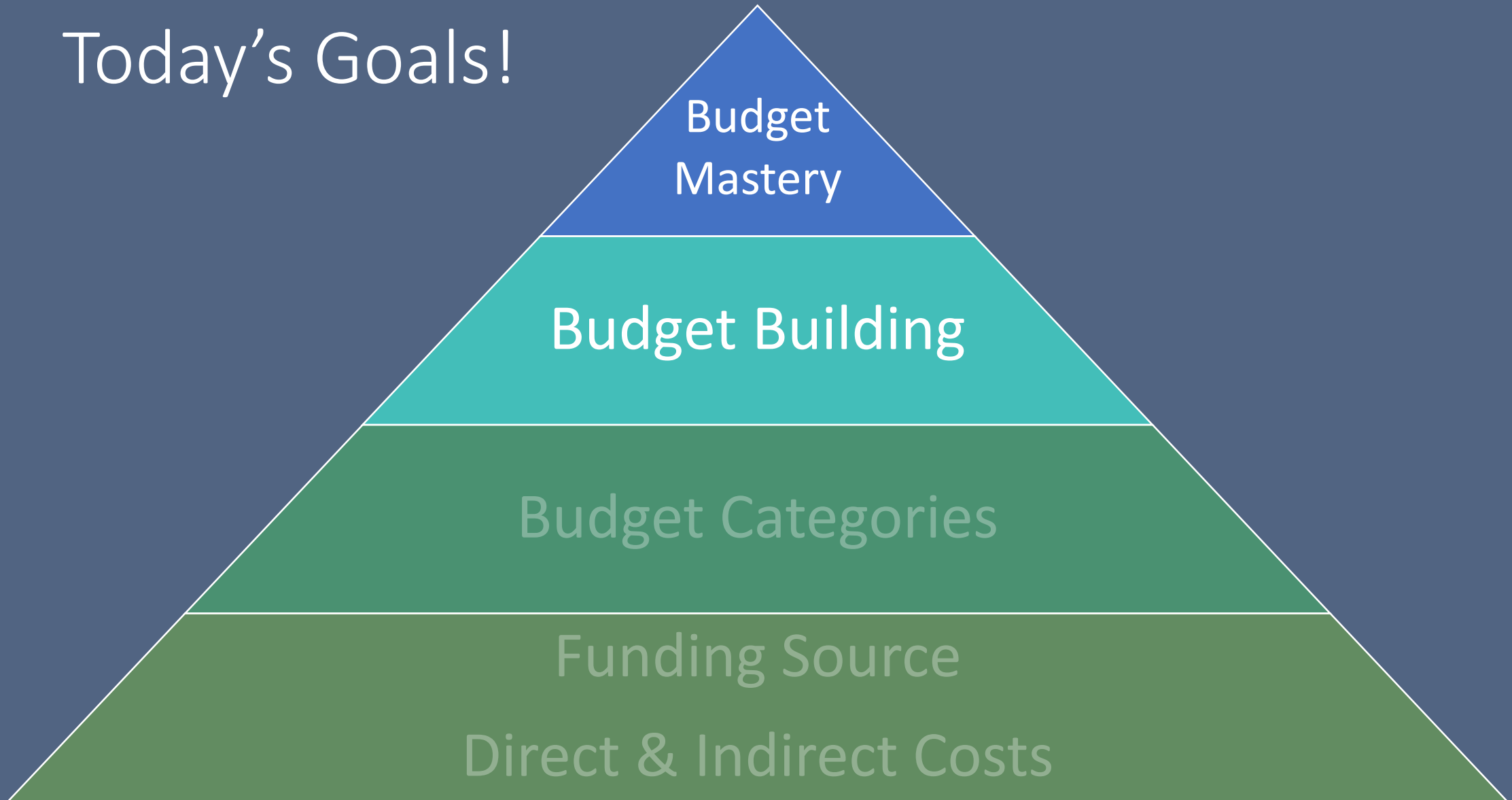
Project Title	NIH Budgets are Fun!			F&A Rate	78.0%		
PI(s)/PD(s)	Inspector Gadget						
Project Period	April 1, 2021- March 31, 2026						
YEAR 1							
Personnel; Project Role	Base Salary	Calendar Months	FTE	Salary Request	Fringe Rate	Fringe Request	Total
Principal Investigator	\$199,300	1.20	0.10	\$19,930	24.70%	\$4,923	\$24,853
Co-Investigator	\$199,300	0.60	0.05	\$9,965	24.70%	\$2,461	\$12,426
Project Manager	\$100,000	3.00	0.25	\$25,000	24.70%	\$6,175	\$31,175
TBN; Research Assistant	\$50,000	12.00	1.00	\$50,000	33.00%	\$16,500	\$66,500
TBN; Biostatistician	\$199,300	6.00	0.10	\$19,930	33.00%	\$6,577	\$26,507
TBN; Research Coordinator	\$60,000	12.00	1.00	\$60,000	33.00%	\$19,800	\$79,800
Name; Role	\$0	0.00	0.00	\$0	0.00%	\$0	\$0
Total Personnel Costs				\$184,825		\$56,436	\$241,261
Consultant Services	Service	Rate		Units	Jnit Type		Total
Name	Service	\$0		0	ours/Days		\$0
Name	Service	\$0		0	ours/Days		\$0
Total Consultant Services							\$0
Travel Costs		Rate		Trips			Total
Scientific Travel		\$2,000		1			\$2,000
Programmatic Travel (local travel)		\$1,000		1			\$1,000
Travel Type		\$0		0			\$0
Total Travel Costs							\$3,000
Patient Costs	Price			Units			Total
Blood work		\$50		200			\$10,000
Cost Type		\$0		0			\$0
Total Patient Costs							\$10,000
Other Direct Costs	Price			Units			Total
Participant payments		\$150		0			\$0
Supplies: Intervention materials		\$50		20			\$1,000
Supplies: computer		\$1,700		2			\$3,400
Publications		\$2,500		1			\$2,500
Cost Type		\$0		0			\$0
Total Other Direct Costs							\$6,900
Consortium Costs							Total
		University of Financial Fun - School of Medicine				Direct	\$150,000
						Indirect	\$84,000
						Total	\$234,000
		University of Financial Fun - School of Public Health				Direct	\$75,000
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Total Direct Consortium Costs					Direct	\$225,000	
Total Indirect Consortium Costs					Indirect	\$126,000	
Total Consortium Costs					Total	\$351,000	
Total Direct Costs							\$486,161
Modified Total Direct Costs							\$286,161
Total Direct and Consortium Costs							\$612,161
Indirect Costs							\$223,206
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Today's Goals!





Budget Building

Elements of a Successful Budget



Scenario #1

- Provide instructions
- Review scenario
- Discuss with your group
- Share thoughts

your work
is going to fill a large part of your life,
and the only way to be truly satisfied is to
do what you believe is
great work.
and the only way to do
great work
is to love what you do.

— Steve Jobs

Where to begin

- Who wrote the protocol?
- How is it funded? (I.e. who is funding the project)
- Who is paying for services?
- What is the expectation around subject injury?
- What type of study is it?
 - Interventional?
 - Observational?
 - Phase?
 - Gene Therapy?
- Where will the visits take place?
- Does the institution have the equipment, personnel and experience to do the study?

Let's Dive In!

- **Indirect Cost Rate:** (= Overhead = Facilities & Administration (F&A)): Costs that represent the expenses of doing business that cannot be easily assigned to a particular project. Determined by institutional policy and source of funding
- **Patient Care Costs:** inpatient or outpatient costs solely for the purpose of the research. Includes labs, tests, scans, etc.
- **Personnel:** Time associated with performing the research activity
 - Total = annual salary + fringe Fringe * number of hours or % effort
- **Materials and Supplies**
 - Intervention supplies (yoga mats, alcohol wipes, pipettes, etc.)
 - Lab kits, dry ice, blood tubes, etc.
 - What is being supplied? What needs to be purchased?

Additional considerations

- **Equipment**: equipment over \$5k, only used for specific project.
 - What is provided? What needs to be purchased?
- **Travel**: investigator meeting, conference (scientific & programmatic)
 - Tips: Include planes, trains and automobiles; hotels; food; # of travelers; # of days; conference fees
- **Recruitment**: advertising or materials such as banners, flyers, branding, etc.
- **Remuneration**: Payments to participants for participation
- **Subawards/Consultant**: Money that will go to another institution. The sub-awardee is a scientific partner who will contribute to decision making.

Budgeting Tools & Important Questions

Budget Tools

- Institutional fees list
 - Charge master
 - Administrative fees
 - Faculty/staff rates
- Coverage analysis
- Protocol
- Budget template
- Informed consent document

Questions to Ask

- What are the effort needs?
- Is it a multi-center study? Is your site the lead site?
- What are the types of tools being used?
- Is there any PI intellectual property? Who wrote the protocol?
- Was there scientific review of the protocol?

Example (UF)

F&A (Indirect) Cost Rates			
F&A (Indirect) Cost Rates			
Research/On campus	52.5% (MTDC)		
Instruction/On Campus	47.5% (MTDC)		
Other Sponsored Activity	32.6% (MTDC)		
All programs / Off-campus	26% (MTDC)		
Industry Sponsored Clinical Trial	30% (TDC)		
TDC base = Total Direct Costs. All direct costs are included. There are no exclusions or modifiers. F&A cost = TDC base x F&A rate.			
MTDC base = Modified Total Direct Costs. TDC minus equipment, patient care, tuition, participant support costs, rental costs of non-UF owned facilities, space, or other property, scholarships, fellowships, and the portion of each subaward in excess of \$25,000. F&A cost = MTDC base x F&A rate.			

Patient Care costs

Budget template

Name	OH?	Total	Selected	
		Quantity	Cost	
Informed Consent Process - Screening		1.00	0.00	
Inclusion/Exclusion Criteria		1.00	0.00	
Initial Visit w Hist, Phys & Vitals		1.00	0.00	
Follow-Up Visit with Physical		9.00	0.00	
Follow-Up Visit Vital Signs		18.00	0.00	
Liver Ultrasound		2.00	0.00	
Target Joint Identification		3.00	0.00	
Hemophilia Joint Health Score		3.00	0.00	
Urinalysis - Sample collection/process/shipment		3.00	0.00	
Blood draw		45.00	0.00	
Hematology CBC w/ Differential		12.00	0.00	
Clinical Chemistry		8.00	0.00	
Alpha Fetoprotein		2.00	0.00	
Lipid Panel if indicated		2.00	0.00	
Factor VIII activity, FVIII antigen		35.00	0.00	
FVIII Inhibitor, VWF Activity, VWF Antigen		2.00	0.00	
aPTT		35.00	0.00	
Liver Function Test		37.00	0.00	
Immunology		24.00	0.00	
HLA genotype		1.00	0.00	
Thiopurine methyltransferase (Local Lab)		1.00	0.00	
Factor VIII activity (Local Lab)		35.00	0.00	

Charge Master (example)

Procedure name	CPT code	Technical fee	Pro fee
BILIRUBIN TOTAL	82247	\$35.00	
BONE MARROW SMEAR	85097	\$1,700.00	
CBC WITH DIFFERENTIAL	85025	\$50.00	
CD34 TOTAL CNTS (PEROPHERAL BLOOD)	86367	\$290.00	
CELL COUNT-HEMPATH	85048	\$20.00	
CMV DNA QUANT BY PCR	87497	\$290.00	
COMPREHENSIVE METABOLIC PANEL	80053	\$75.00	
CORTISOL	82533	\$110.00	
CPK	82550	\$45.00	
CREATININE CLEARANCE (24 HOUR URINE)	82575	\$65.00	
CRP – HIGH SENSITIVITY	86141	\$90.00	
CYSTATIN C	82610	\$75.00	
DECALCIFICATION	88311	\$45.00	
DIRECT BILIRUBIN	82248	\$35.00	
FACTOR VIII ACTIVITY	85240	\$120.00	
FACTOR VIII INHIBITOR	85335	\$85.00	
FERRITIN	82728	\$95.00	

Procedure name	CPT code	Tech fee	Pro Fee
Bilateral lower extremity MRI ANKLE w/ contrast	73722	\$1,900.00	\$650.00
Bilateral lower extremity MRI ANKLE w/o contrast	73721	\$1,200.00	\$320.00
Bilateral lower extremity MRI KNEE w/ contrast	73722	\$1,950.00	\$125.00
Bilateral lower extremity MRI KNEE w/o contrast	73721	\$1,000.00	\$225.00
Body Composition (DXA)	77080	\$450.00	\$125.00
Cardiac Flow mapping - add on	75565	\$450.00	
Cardiac MRI - morphology & function w/o & w/Contrast	75561	\$2,200.00	\$689.00
Chest X-ray	71045	\$125.00	\$49.00
Gadolinium MRI Contrast (Multihance)	A9579	\$75.00	
Gadolinium MRI Contrast per ml	A9579	\$5.00	
Gadolinium MRI Contrast per ml	A9575	\$65.00	
Imaging (CD's)		\$15.00	

Standard Fees

START-UP FEES		
Administrative Review & Start-up	\$4,000	A non-refundable fee for study personnel time & effort devoted to conducting an administrative review of the protocol and related documents; attending pre-activation meetings; coordinating site visits; completing study-required training; conducting site training; and, consultations with sponsor/CRO.
IRB & Regulatory Processing	\$3,000	A non-refundable fee for study personnel time & effort devoted to obtaining all approvals required for site activation including processing submissions to ancillary review committees; processing the initial IRB submission; and, preparing and submitting all regulatory documentation. <i>IRB review fees, if any, are not included in this fee.</i>
Protocol Feasibility & Scientific Review	\$3,500	A non-refundable fee for study personnel time & effort devoted to evaluating the protocol and related documents for site appropriateness, availability of subject population, study overlap, and access to appropriate resources (staff, facilities, equipment, etc.).
PI Oversight	\$3,000	A non-refundable fee for the Principal Investigator's time and effort devoted to supervising the research; ensuring that the research is conducted in accordance with all federal, state, and local laws and regulations, institutional policies, and the requirements of the IRB; delegating tasks to individuals qualified by education, experience, and training; reviewing and signing-off on study-related documents; meeting with study staff to discuss subjects, adverse events, and treatment; and consultations with sponsor/CRO.
Budgeting	\$3,000	A non-refundable fee for study personnel time & effort devoted to reviewing the protocol and schedule of events; conducting a Medicare Coverage Analysis; obtaining procedure codes and costs for study-funded services; and, creating and negotiating the study budget.
Contracting	\$2,500: New agreement \$750: Rider to master agreement	A non-refundable fee for study personnel time & effort devoted to reviewing, negotiating, and executing the study agreement.
CTMS Setup	\$2,000	A non-refundable fee for study personnel time & effort devoted to entry of protocol, calendar, and budget into institutionally mandated web-based clinical research management system, OnCore. OnCore serves as the source of truth for all research-related activities including regulatory management, subject management, billing compliance tracking, sponsor invoicing, and accounts receivable management.
Investigational Drug Service	TBD	A non-refundable fee for pharmacy time & effort devoted to protocol implementation; building study drug orders in electronic medical record; receipt of investigational product; climate-controlled storage of investigational product; maintenance and organization of study related documents; accessing computer based system for subject or study drug assignment; completing study-required training; and, consultations with sponsor/CRO.
Clinical Research Center	TBD	A non-refundable fee for study personnel time & effort devoted to conducting a scientific & feasibility review of the protocol and implementing the study in the Clinical Research Center.
WIRB Initial Review	As billed	Sponsor should be invoiced directly and remit payment to WIRB. If fees are passed through UF, institutional overhead along with a 10% administrative processing fee will apply.

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ANNUAL FEES		
Administrative & Regulatory Maintenance	\$4,500	Annual non-refundable fee for study personnel time & effort devoted to invoicing, accounts receivable, and sponsor payment processing; accounts payable processing through institution; financial account management; preparation & submission of new/updated regulatory documents; maintenance of regulatory binder; routing of all hospital and physician charges; paying of all hospital and physician study-funded charges; and, processing of subject travel reimbursement.
WIRB Continuing review	As billed	Sponsor should be invoiced directly and remit payment to WIRB. If fees are passed through MU, institutional overhead along with a 10% administrative processing fee will apply.
Investigational Drug Service Maintenance	TBD	Annual non-refundable fee for pharmacy time & effort devoted to processing of revisions; sponsor correspondence; addressing drug related issues; ordering investigational product; maintaining drug accountability records and shipping receipts; climate-controlled storage of drug and used investigational product; and, accessing computer based system for subject or study drug assignment.
PER OCCURRENCE FEES		
IRB Continuing Renewal	\$750	A per renewal fee for study personnel time & effort devoted to completing and submitting the IRB continuing review application and responding to inquiries regarding the submission.
Site Monitor Change	\$875	A per change fee for study personnel time & effort devoted to obtaining electronic medical record (EMR) access for the new monitor; training the new monitor on EMR navigation; and, addressing any outstanding issues/queries.
Site Monitoring	\$750	A per monitoring visit fee for study personnel time & effort devoted to working with monitor to verify case report form data and responding to inquiries regarding entered data.
		A per report fee for study personnel time & effort devoted to

Personnel Costs

Budgeting Tool

	A	B	C	D	E	F	G	H	I
1	Staff Hourly Rates	Base	Fringe	Total	Rounded Total				
2	Investigator	\$ 225.00	\$ 45.00	\$ 270.00	\$ 270.00				
3	Admin Director	\$ 90.00	\$ 36.00	\$ 126.00	\$ 125.00		Fringe	2021	
4	Assist Director	\$ 80.00	\$ 32.00	\$ 112.00	\$ 110.00		COM Faculty	0.2	
5	Study Nurse	\$ 65.00	\$ 26.00	\$ 91.00	\$ 90.00		TEAMS E	0.4	
6	Study Coordinator	\$ 55.00	\$ 22.00	\$ 77.00	\$ 75.00		TEAMS NE	0.5	
7	Data Manager	\$ 35.00	\$ 17.50	\$ 52.50	\$ 55.00				
8	Clinical Research Manag	\$ 75.00	\$ 30.00	\$ 105.00	\$ 105.00				
9	Protocol Activation	\$ 55.00	\$ 22.00	\$ 77.00	\$ 75.00				
10	Finance Specialist	\$ 50.00	\$ 20.00	\$ 70.00	\$ 70.00				
11	Contract Analyst	\$ 50.00	\$ 20.00	\$ 70.00	\$ 70.00				
12	Reg Coordinator	\$ 35.00	\$ 17.50	\$ 52.50	\$ 55.00				
13	Marketing Coordinator	\$ 50.00	\$ 20.00	\$ 70.00	\$ 70.00				
14	Research Administrator	\$ 35.00	\$ 17.50	\$ 52.50	\$ 55.00				
15	Admin Assistant	\$ 25.00	\$ 12.50	\$ 37.50	\$ 40.00				
16				Round to nearest	\$5				
17									
18									

Budgeting Tool

Team Effort for Budgeting								
Staff	Hourly Rate	Screening	Tx Complex	Tx Complex (beyond V1)	Tx Simple	End of Tx	F/U Complex	F/U Simple
Principal Investigator	\$225.00	2 Hrs	2 Hrs	1 Hr	1 Hr	2 Hrs	1 Hr	0.5 Hr
Study Coordinator	\$65.00	8 Hrs	8 Hrs	4 Hrs	2 Hrs	8 Hrs	2 Hr	1 Hr
Data Manager	\$45.00	4 Hrs	4 Hrs	3 Hrs	2 Hrs	4 Hrs	2 Hr	1 Hr

Budgeting Tool

Activity	Personnel	Unit Cost	# Units	Sub Total	30.0%	Total	Rounded Total	Cost without OH
Consent	Investigator	\$ 270.00	1	\$ 270.00	\$ 81.00	\$ 351.00		
	Study Coordinator	\$ 75.00	1	\$ 75.00	\$ 22.50	\$ 97.50		
						\$ 448.50	\$ 450.00	\$ 346.15
Eligibility Review	Investigator	\$ 270.00	0.5	\$ 135.00	\$ 40.50	\$ 175.50		
	Clinical Research Manager	\$ 105.00	0.5	\$ 52.50	\$ 15.75	\$ 68.25		
	Study Coordinator	\$ 75.00	2	\$ 150.00	\$ 45.00	\$ 195.00		
						\$ 438.75	\$ 440.00	\$ 338.46
Randomization	Study Coordinator	\$ 75.00	1	\$ 75.00	\$ 22.50	\$ 97.50	\$ 100.00	\$ 76.92
Research Blood Sample	Study Coordinator	\$ 75.00	1	\$ 75.00	\$ 22.50	\$ 97.50		
	Data Manager	\$ 55.00	0.5	\$ 27.50	\$ 8.25	\$ 35.75		
						\$ 133.25	\$ 135.00	\$ 103.85
Questionnaire	Study Coordinator	\$ 75.00	0.5	\$ 37.50	\$ 11.25	\$ 48.75		
	Data Manager	\$ 55.00	0.5	\$ 27.50	\$ 8.25	\$ 35.75		
						\$ 84.50	\$ 85.00	\$ 65.38
Adverse Events	Investigator	\$ 270.00	0.25	\$ 67.50	\$ 20.25	\$ 87.75		
	Study Coordinator	\$ 75.00	0.25	\$ 18.75	\$ 5.63	\$ 24.38		
	Data Manager	\$ 55.00	0.25	\$ 13.75	\$ 4.13	\$ 17.88		
						\$ 130.00	\$ 130.00	\$ 100.00
Con Meds	Study Coordinator	\$ 75.00	0.5	\$ 37.50	\$ 11.25	\$ 48.75		
	Data Manager	\$ 55.00	0.25	\$ 13.75	\$ 4.13	\$ 17.88		
						\$ 66.63	\$ 65.00	\$ 50.00

Personnel – Federal Funding

- **Personnel:**

- Requested salary = Base salary x % Effort
- Requested fringe = Requested salary x Fringe rate
- Total = Requested salary + Requested Fringe
- Tip: is there a salary cap?

YEAR 1							
Personnel; Project Role	Base Salary	Calendar Months	FTE	Salary Request	Fringe Rate	Fringe Request	Total
Principal Investigator	\$199,300	1.20	0.10	\$19,930	24.70%	\$4,923	\$24,853
Co-Investigator	\$199,300	0.60	0.05	\$9,965	24.70%	\$2,461	\$12,426
Project Manager	\$100,000	3.00	0.25	\$25,000	24.70%	\$6,175	\$31,175
TBN; Research Assistant	\$50,000	12.00	1.00	\$50,000	33.00%	\$16,500	\$66,500
TBN; Biostatistician	\$199,300	6.00	0.10	\$19,930	33.00%	\$6,577	\$26,507
TBN; Research Coordinator	\$60,000	12.00	1.00	\$60,000	33.00%	\$19,800	\$79,800
Name; Role	\$0	0.00	0.00	\$0	0.00%	\$0	\$0
Total Personnel Costs				\$184,825		\$56,436	\$241,261

Travel Costs		Rate		Trips			Total
Scientific Travel		\$2,000		1			\$2,000
Programmatic Travel (local travel)		\$1,000		1			\$1,000
Travel Type		\$0		0			\$0
Total Travel Costs							\$3,000
Patient Costs		Price		Units			Total
Blood work		\$50		200			\$10,000
Cost Type		\$0		0			\$0
Total Patient Costs							\$10,000

Review Scenario #1

- Provide instructions
- Review scenario
- Discuss with your group
- Share thoughts

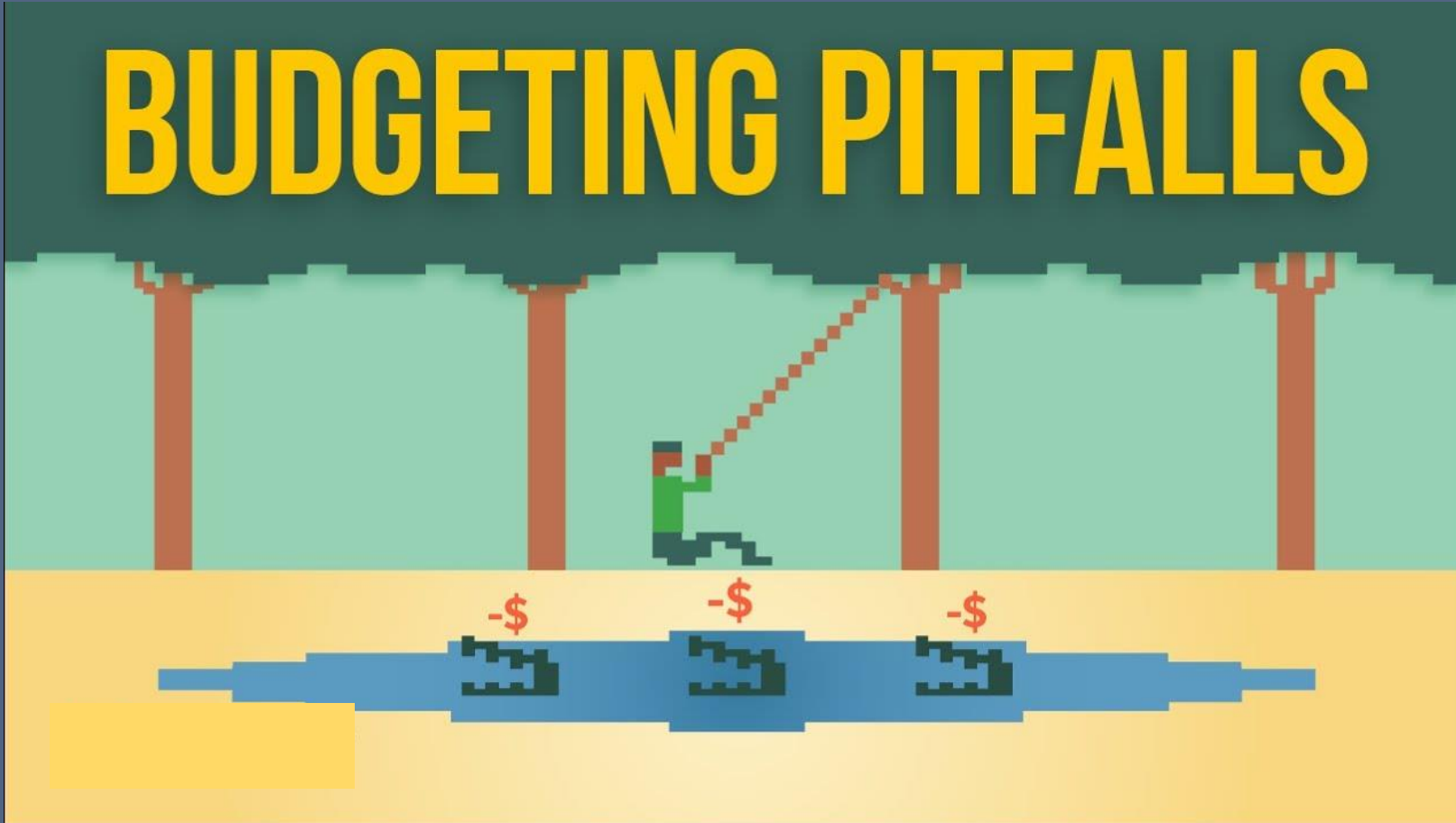
your work
is going to fill a large part of your life,
and the only way to be truly satisfied is to
do what you believe is
great work.
and the only way to do
great work
is to love what you do.

— Steve Jobs

What do you think are the most common budgeting missteps?

- Type your responses into the chat
- Add your comments on the slide (use Zoom annotate feature)

BUDGETING PITFALLS



Budgeting Pitfalls

- Finalizing a budget before coverage analysis is complete
- Making assumptions
- Not asking follow-up questions
- Missing information needed to determine costs
- Not recruiting fast enough
- Not performing feasibility
- Not pricing out the activities listed in the SOE/SOA
- Not including OH or it is calculated incorrectly
- Not double checking formulas
- Not willing to walk away
- Salary caps
- Budget caps
- Not allocating enough staff time
- Not including all the costs
- Underestimate time to complete activities
- Budget template doesn't match the SOE
- Underestimating the cost of recruitment
- Not performing feasibility

Budgeting Best Practices

- Think win-win
- Start when you have all the information
- Review all the calculations carefully
- Ensure OH is calculated/included
- Be sure the costs are covered
- Communicate with the team
- Be willing to walk away if not financially feasible
- Review predicted vs actuals at intervals
- Learn Excel

Questions?



Images

- [Budget Pitfalls](#)
- [Questions](#)
- [Elements of Successful Budget](#)