Clinical Research Budgets The Fundamentals

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Boston University/Boston Medical Center

Disclosures & Disclaimers

No disclosures

- Disclaimers & Finance Experience
 - Jessica: No formal finance training, just 17 years of Clinical Research experience
 - Rebeccah: 10+ years in business and finance, 10 years in Clinical Research experience

What best describes your reaction to Excel and budgeting?

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)

Objectives

- 1. Identify major budget categories
- 2. Define important budget terms
- 3. Recognize common budgeting pitfalls

What do you hope to learn today?

- We will put a link in the Chat for Google Jamboard
- Menu on left: Use the sticky note option (4th icon down)
- Choose your color(s) and start adding sticky notes!



Get Down with Budgeting Lexicon



Budget Mastery

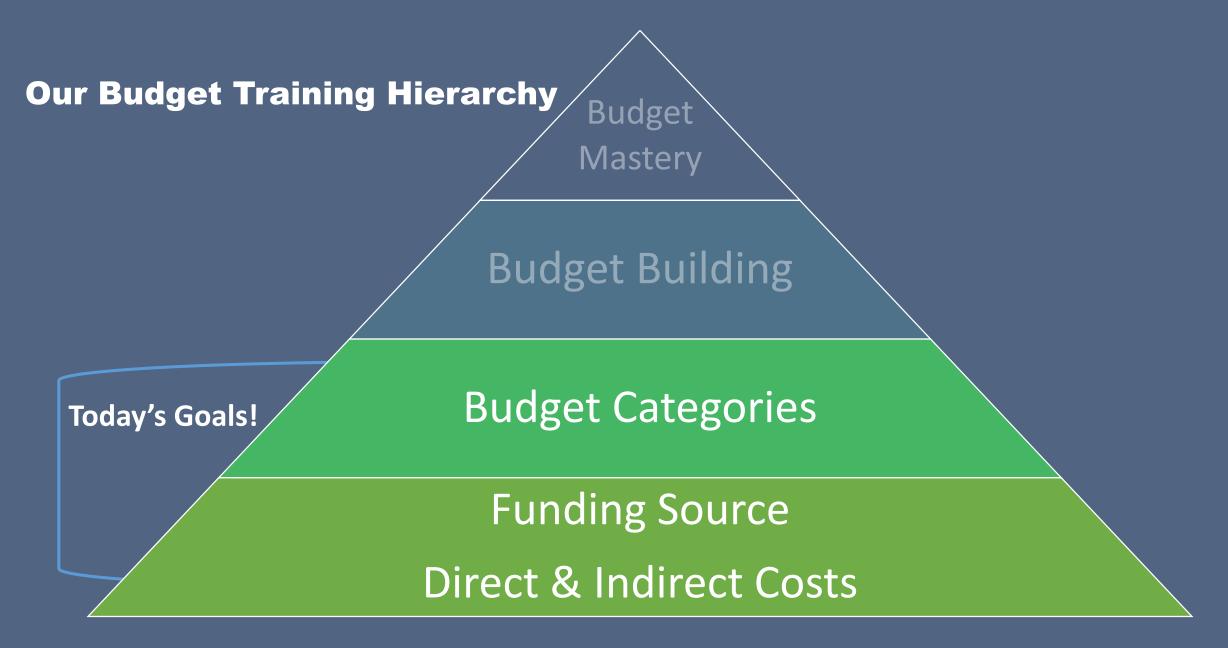
Budget Building

Budget Categories

Funding Source

Direct & Indirect Costs

Project Title	NIH Budget	s are Fun!		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector G	adget					
Project Period	April 1, 202	1- March 3	1, 2026				
YEAR 1							
	Base	Calendar		Salary	Fringe	Fringe	
Personnel; Project Role	Salary	Months	FTE	Request	Rate	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		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/Day	/S	\$0
Name	Service	\$0		0	ours/Day	/S	\$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		Ç.					\$3,000
Patient Costs		Price		Units			Total
Blood work		\$50		200			\$10,000
Cost Type		\$0		0			\$10,000
Total Patient Costs		Ţ.					\$10,000
Other Direct Costs		Price		Units			Total
Participant payments		\$150		0			\$0
Supplies: Intervention		7130					, JO
		¢E0		20			¢1 000
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 Consortium Costs							\$6,900
Consortium Costs	University	of Einancial	Eup Sal	and of Mad	icine	Direct	Total \$150,000
	Offiversity C	oi Filialiciai	ruii - Sci	nool of Med	icine	Indirect	\$84,000
						Total	\$234,000
	University	of Financial	Fun - Sch	nool of Publi	ic Health		\$75,000
	Offiversity C	2. I mancial	501	.cor or r ubii	e ricaitii	Indirect	\$42,000
						Total	\$117,000
Total Direct Consortium Costs						Direct	\$225,000
Total Indirect Consortium Costs						Indirect	\$126,000
Total Consortium Costs						Total	\$351,000
Total Collsol Halli Costs						. Otal	7331,000
Total Direct Costs							\$486,161
Modified Total Direct Costs							\$286,161
Total Direct and Consortium (`osts						\$612,161
Indirect Costs	.0313						\$223,206
Total Costs							\$835,367



Pick Your Adventure: Funder & Cost Categories

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

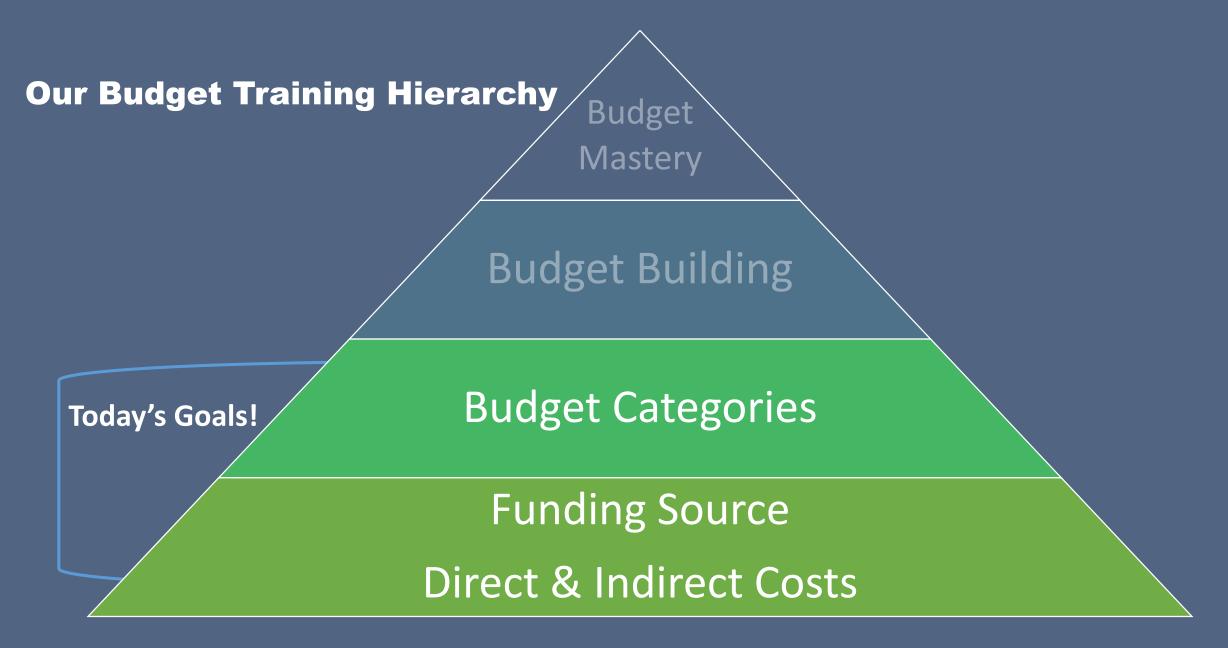
Direct & Indirect Costs Examples

DIRECT Costs

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

INDIRECT Costs

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



What do you think the major budget categories are?

- We will put a link in the Chat for Google Jamboard
- Menu on left: Use the sticky note option (4th icon down)
- Choose your color(s) and start adding sticky notes!

Major/Most Common Clinical Trial Budget Categories*

- Personnel
- Equipment
- Travel
- Research Patient Care Costs
- Materials and Supplies
- Recruitment
- Remuneration
- Subawards
- Indirect Costs

Project Title	NIH Budget	s are Fun!		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector G	iadget					
Project Period	Аргіі 1, 202	21- March 3	1, 2026				
YEAR 1							/
	Base	Calendar		Salary	Fringe	Fringe	
Personnel; Project Role	Salary	Months	FTE	Request	Rate	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
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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/Day	ys	\$0
Name	Service	\$ 0		0	ours/Day	ys	\$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		7.5					\$6,900
Consortium Costs							Total
	University	of Financial	Fun - Scl	nool of Med	icine	Direct	\$150,000
	,					Indirect	\$84,000
						Total	\$234,000
	University	of Financial	Fun - Scl	hool of Publ	ic Health	Direct	\$75,000
						Indirect	\$42,000
						Total	\$117,000
Total Direct Consortium Costs						Direct	\$225,000
Total Indirect Consortium Cos						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
Total Costs							\$835,367
TOTAL COSTS							3033,30 <i>/</i>

Let's Dive In!

• Personnel:

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

YEAR 1							
	Base	Calendar		Salary	Fringe	Fringe	
Personnel; Project Role	Salary	Months	FTE	Request	Rate	Request	Total
Principal Investigator	\$199,300	1.20	0.10	\$19,930	24.70%	\$4,923	\$24,853
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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

Let's Dive In!

• **Equipment**: over \$5k, only used for specific project

- **Travel**: scientific & programmatic
 - Tips: Include planes, trains and automobiles; hotels; food; # of travelers; # of days; conference fees
- Research Patient Care Costs: inpatient or outpatient costs solely for the purpose of the research. Includes labs, tests, scans, etc.

Project Title	NIH Budget	s aro Eunl		F&A Rate	78.0%		
Project Title	NIH Budget			raa nate	78.0%		
PI(s)/PD(s) Project Period	Inspector G April 1, 202		1 2026				
YEAR 1	April 1, 202	.1- Warch 3	1, 2020				
TEAN I	D	Calandan		Calami	F	F	
B B B	Base	Calendar		Salary	Fringe	Fringe	
Personnel; Project Role	Salary	Months	FTE	Request	Rate	Request	Total
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Project Manager TBN; Research Assistant	\$100,000 \$50,000	3.00 12.00	1.00	\$25,000 \$50,000		\$6,175 \$16,500	\$31,175 \$66,500
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Name; Role	\$60,000	0.00	0.00		0.00%	\$19,800	\$79,800
Total Personnel Costs	\$ 0	0.00	0.00	\$1 0-1,82 5		\$56,436	\$241,261
Consultant Services	Service	Rate		Units	Jnit Type		Total
Name	Service	\$0		0	ours/Day		\$0
Name	Service	\$0 \$0		0	ours/Day		\$0 \$0
Total Consultant Services	Service	Ų.		J	ours/ Day	, 5	\$0
Travel Costs		Rate		Trips			Total
Scientific Travel		\$2,000		1			\$2,000
Programmatic Travel (local		\$2,000					72,000
· ·		¢1.000		1			¢1.000
travel)		\$1,000		1			\$1,000
Travel Type		\$0		0			\$0
Total Travel Costs		Duine					\$3,000
Patient Costs		Price		Units			Total
Blood work		\$50		200			\$10,000
Cost Type Total Pationt Costs		\$0		0			\$0 \$10,000
Other Direct Costs		Price		Units			Total
		\$150		Offics			
Participant payments		\$150					\$0
Supplies: Intervention		4					4
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	of Financial	Fun - Sch	nool of Med	icine	Direct	\$150,000
						Indirect	\$84,000
		. (= 1	F . C.I			Total	\$234,000
	University	of Financial	Fun - Sch	nool of Publ	ic Health		\$75,000
						Indirect	\$42,000
Tatal Dinast Carry III Carry						Total	\$117,000
Total Direct Consortium Costs						Direct	\$225,000
Total Indirect Consortium Cos	is					Indirect	\$126,000
Total Consortium Costs						Total	\$351,000
							4
Total Direct Costs							\$486,161
Modified Total Direct Costs							\$286,161
Total Direct and Consortium (Costs						\$612,161
Indirect Costs							\$223,206
Total Costs							\$835,367

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

Let's Dive In!

- Materials and Supplies
 - Intervention supplies (yoga mats, alcohol wipes, pipettes, etc.)
 - CAN be staff computers
- **Recruitment**: advertising or materials such as banners, flyers, branding, etc.
- **Remuneration**: Payments to participants for participation
- <u>Subawards</u>: Money that will go to another institution. The sub-awardee is a scientific partner who will contribute to decision making.

Project Title	NIH Budget	s are Funl		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector G			I GA Rate	70.070		
Project Period		11- March 3:	1 2026				
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Davis at Dala				-		_	Total
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					Jnit Type		
Name	Service	\$0		0	ours/Day		\$0
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Total Consultant Services		D-4-		T			
Travel Costs		Rate		Trips			Total
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Programmatic Travel (local							
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Travel Type		\$0		0			\$0
Total Travel Costs							\$3,000
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Cost Type		\$0		0			\$0
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Other Direct Costs		Price		Units			Total
Participant payments		\$150		0			\$0
Supplies: Intervention							
materials		\$50		20			\$1,000
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Publications		\$2,500		1			\$2,500
Cost Type		\$0		0			\$0
Total Other Direct Costs							\$6,900
Consortium Costs							Total
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	·					Indirect	\$84,000
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Total Direct Consortium Costs	5					Direct	\$225,000
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Supplies: Intervention							
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Total Direct Consortium Costs						Direct	\$225,000
Total Indirect Consortium Cos	ts					Indirect	\$126,000
Total Consortium Costs						Total	\$351,000

Indirect Cost RATE

- <u>Direct Costs</u>: Costs that can be directly assigned to a particular project, are *necessary*, reasonable and ALLOWABLE.
- Indirect Costs (F&A): Costs that represent the expenses of doing business that cannot be easily assigned to a particular project.

Indirect cost RATES are determined by the funder

- A cognizant federal agency sets our institutions' rates, which are negotiated, fixed for a period of time & differ based on project type.
- Foundations will often have their own set rate.

Example (BU)

F&A (Indirect) Cost Rates

F&A (Indirect) Cost Rates	July 1, 2018 - June 30, 2023
Research/On-campus	65.0%
Instructional and training/On-campus	53.0%
Other Sponsored Awards	39.0%
All programs/Off-campus	26.0%
Clinical Trials	30.0% TDC

Indirect Cost Exclusions (NIH Specific)

- Tuition
- Equipment over \$5k
- Participant patient care costs
- Subaward charges after \$25k

Personnei; Project Kole	Salary	iviontns	FIE	Kequest	Kate	Kequest	rotai
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Name	Service	\$0		0	ours/Day	ys	\$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		Ψ.					\$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		\$100					ΨC
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 Consortium Costs							\$6,900
Consortium Costs	Linivarsity	of Financial	Tum Cak	nool of Med	inina	Direct	Total \$150,000
	University (oi Financiai	run - Sci	iooi oi ivied	icine	Indirect	\$150,000
						Total	\$234,000
	Linivarsity	of Financial	Tun Cak	and of Dubl	ia I I aal+b		
	University (oi Financiai	run - Sci	nool of Publ	іс пеаіті	Indirect	\$75,000 \$42,000
						Total	\$117,000
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Total Consortium Costs						Total	\$351,000
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Total Direct Costs							\$486,161
Modified Total Direct Costs							\$286,161
Total Direct and Consortium C	osts						\$612,161
Indirect Costs							\$223,206
Total Costs							\$835,367

Determining your Indirect Cost

- <u>Direct Costs</u>: Costs that can be directly assigned to a particular project, are *necessary*, reasonable and ALLOWABLE.
- <u>Indirect Costs (F&A)</u>: Costs that represent the expenses of doing business that cannot be easily assigned to a particular project.
- 1. Add all direct costs
- Subtract all <u>excluded</u> direct costs (i.e., tuition, equipment over \$5k, participant patient care costs, subaward charges after \$25k) = <u>Modified Total Direct Costs (MTDC)</u>
- 3. Take MTDC x Indirect cost rate = Indirect costs!

Put Me in Coach!

- 1. Add all your site's (BMC) direct costs
- 2. Subtract all <u>excluded</u> direct costs (i.e., tuition, equipment over \$5k, participant patient care costs, subaward charges after \$25k) = Modified Total Direct Costs (MTDC)
- 3. Take MTDC x Indirect cost rate = Indirect costs!
- 4. Total costs = Indirect Costs + BMC Total Direct Costs

What are your TOTAL COSTS?

Project Title	NIH Budgets	are Fun!		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector Ga	_					
Project Period	April 1, 202	1- March 31	, 2026				
YEAR 1							
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Personnel; Project Role	Base Salary	Months	FTE	Request	Rate	Request	Total
Principal Investigator	\$199,300	1.20	0.10	\$19,930	24.70%	\$4,923	\$24,853
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Name; Role	\$0	0.00	0.00	\$0	0.00%	\$0	\$0
Total Personnel Costs				\$79,930		\$24,723	\$104,653
Consultant Services	Service	Rate		Units	Jnit Type	:	Total
Name	Service	\$0		0	Hours/D	ays	\$0
Total Consultant Services							\$0
Travel Costs		Rate		Trips			Total
Scientific Travel		\$2,000		1			\$2,000
Total Travel Costs							\$2,000
Patient Costs		Price		Units			Total
Blood work		\$50		200			\$10,000
Total Patient Costs							\$10,000
Other Direct Costs		Price		Units			Total
Participant payments		\$150		0			\$0
Supplies: Intervention materials		\$50		20			\$1,000
Publications		\$2,500		1			\$2,500
Cost Type		\$0		0			\$0
Total Other Direct Costs							\$3,500
BMC Total Direct Costs							
Modified Total Direct Costs							
Indirect Costs (78%)							
Total Costs							

Project Title	NIH Budgets	are Funi		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector Ga			T GOT HULL	70.070		
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Total Personnel Costs	ų o	0.00	0.00	\$79,930		\$24,723	\$104,653
Consultant Services	Service	Rate			Jnit Type		Total
Name	Service	\$0		0	Hours/D		\$0
Total Consultant Services		7-		_		-,-	\$0
Travel Costs		Rate		Trips			Total
Scientific Travel		\$2,000		1			\$2,000
Total Travel Costs		T = / = = =		_			\$2,000
Patient Costs		Price		Units			Total
Blood work		\$50		200			\$10,000
Total Patient Costs							\$10,000
Other Direct Costs		Price		Units			Total
Participant payments		\$150		0			\$0
Supplies: Intervention materials		\$50		20			\$1,000
Publications		\$2,500		1			\$2,500
Cost Type		\$0		0			\$0
Total Other Direct Costs							\$3,500
BMC Total Direct Costs							\$120,153
Modified Total Direct Costs							\$110,153
Indirect Costs (78%)							\$85,919
Total Costs							\$206,072

Project Title	NIH Budget	s are Fun!		F&A Rate	78.0%		
PI(s)/PD(s)	Inspector G						
Project Period	April 1, 202		1. 2026				
YEAR 1	,						
	Base	Calendar		Salary	Fringe	Fringe	
Personnel; Project Role	Salary	Months	FTE	Request	Rate	Request	Total
Principal Investigator	\$199,300	1.20	0.10	\$19,930		\$4,923	\$24,853
Co-Investigator	\$199,300	0.60	0.10		24.70%	\$2,461	\$12,426
Project Manager	\$100,000	3.00	0.05	\$25,000		\$6,175	\$31,175
TBN; Research Assistant	\$50,000	12.00	1.00	\$50,000			\$66,500
				\$19,930		\$6,577	
TBN; Biostatistician	\$199,300	6.00	0.10				\$26,507 \$79,800
TBN; Research Coordinator	\$60,000	12.00	1.00	\$60,000		\$19,800	
Name; Role	\$0	0.00	0.00		0.00%	\$0	\$0
Total Personnel Costs	C	D-4-		\$184,825	India Toma	\$56,436	\$241,261
Consultant Services	Service	Rate			Jnit Type		Total
Name	Service	\$0			ours/Day		\$0
Name	Service	\$0		0	ours/Day	/S	\$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		7130					ΨŪ
		¢E0		20			¢1 000
materials		\$50					\$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	of Financial	Fun - Scl	nool of Med	icine	Direct	\$150,000
						Indirect	\$84,000
						Total	\$234,000
	University of	of Financial	Fun - Scl	nool of Publ	ic Health		\$75,000
						Indirect	\$42,000
						Total	\$117,000
Total Direct Consortium Cost	S					Direct	\$225,000
Total Indirect Consortium Co	sts					Indirect	\$126,000
Total Consortium Costs						Total	\$351,000
Total Direct Costs							\$486,161
Modified Total Direct Costs							\$286,161
	Costs						\$612,161
Total Direct and Consortium	COSIS						
Indirect Costs							\$223,206
Total Costs							\$835,367

What do you think are the most common budgeting missteps?

- We will put a link in the Chat for Google Jamboard
- Menu on left: Use the sticky note option (4th icon down)
- Choose your color(s) and start adding sticky notes!

Forgetting travel

Salary caps

Budgeting Pitfalls

Budget caps

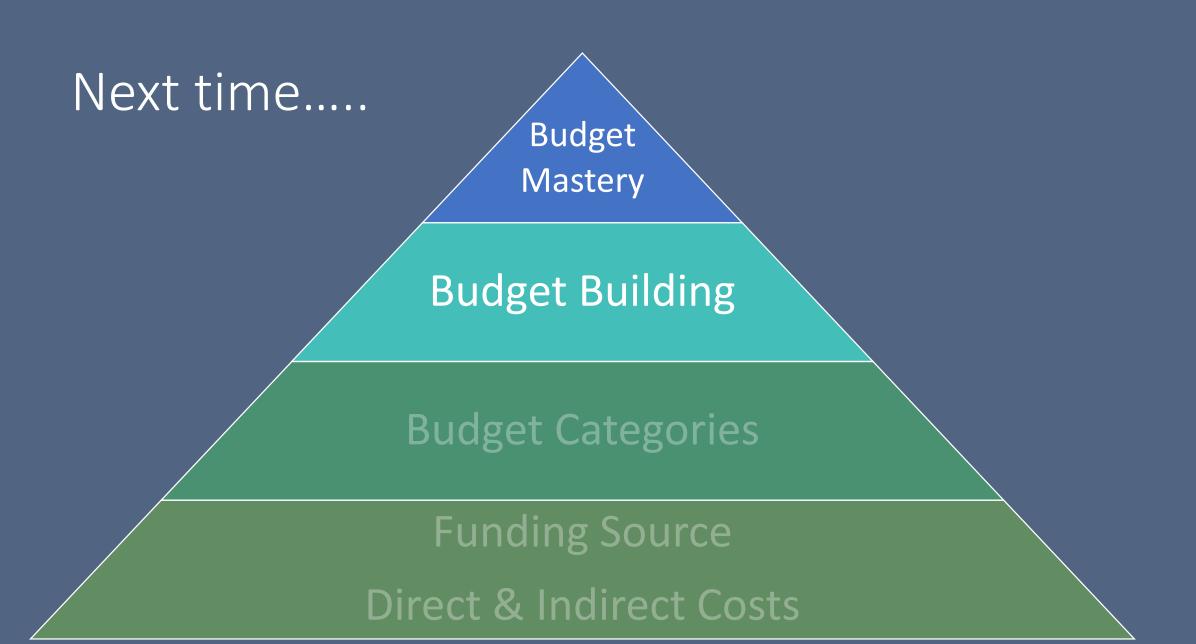
Not planning for attrition

Underestimating time

Not allocating enough staff time

Missing information needed to determine costs

Which one of these lists includes ONLY *direct* costs that are always allowable by any funding source?



Next time.....

Budget Mastery

Budget Building

QUESTIONS!

Budget Categories

Funding Source

Direct & Indirect Costs

Definition Resource:

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#difference

Examples of Direct and Indirect costs:

https://www.uvm.edu/sites/default/files/Division-of-

<u>Finance/cost_accounting/Typical_Direct_and_Indirect_Costs.pdf</u>

Institutional links for budgets

Institution	Links
BU	http://www.bu.edu/researchsupport/tools-services/facilities-administrative/ https://www.bu.edu/researchsupport/2020/06/25/updated-fringe-benefit-rates-for-fy-2021-and-provisional-rates-for-fy-2022/
ВМС	https://www.bmc.org/research-operations/pre-award https://www.bmc.org/sites/default/files/Research/13.Facility-admin-costs08.doc
UVM	F&A and benefit Rates for website 6.19.20.xlsx (uvm.edu)
UF	Facilities & Administrative (F&A) or Indirect Costs (IDC) Budgeting Overview
MUSC	https://research.musc.edu/resources/orsp/proposal-preparation/useful-institutional-info