

Clinical Research Budgets *The Fundamentals*

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Disclosures & Disclaimers

- No disclosures
- Disclaimers & Finance Experience
 - Jessica: No formal finance training, just 17 years of Clinical Research experience
 - Rebecca: 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

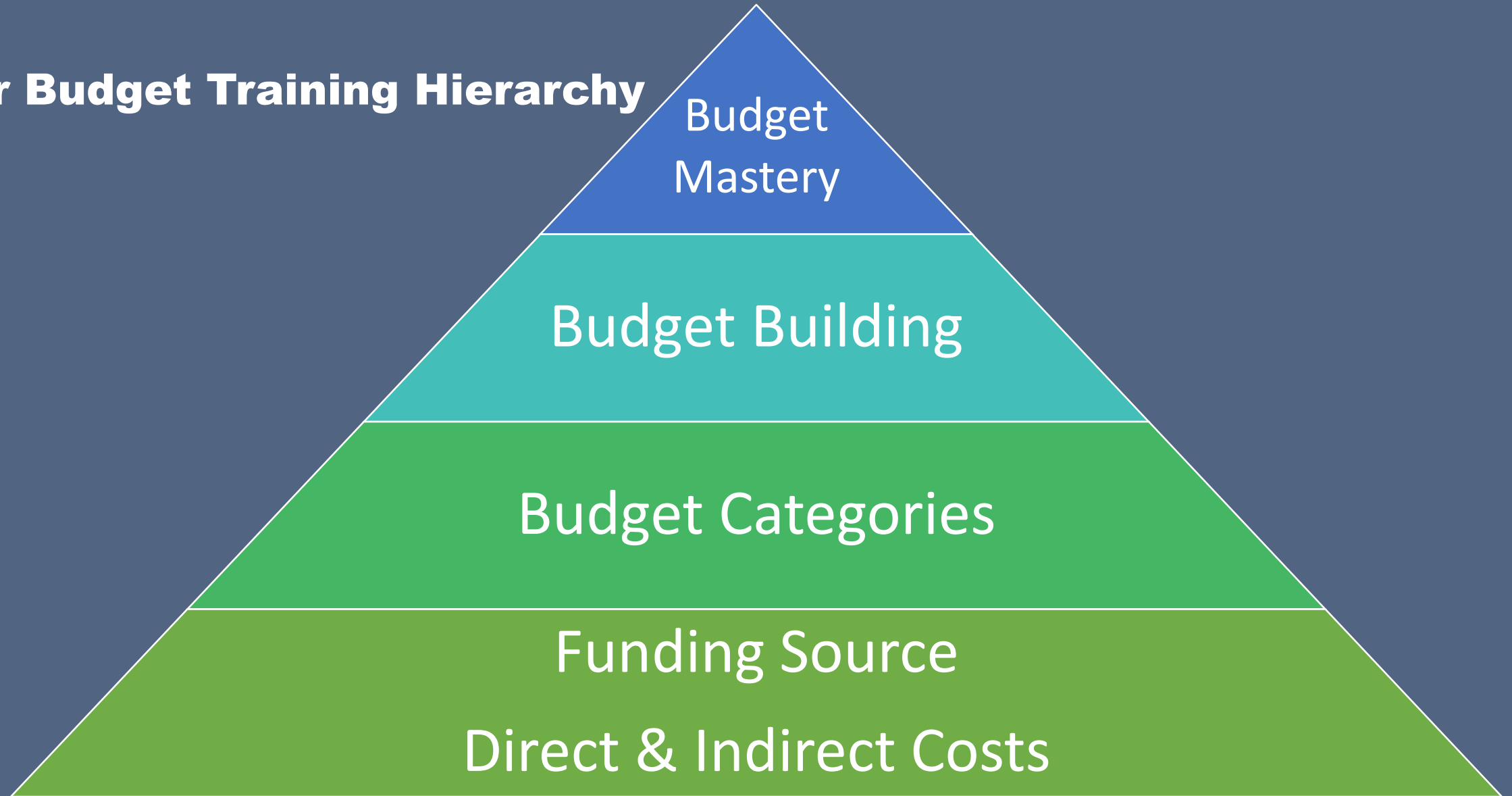
What do you hope to learn today?

- 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

Our Budget Training Hierarchy



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	Unit 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
						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 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

Our Budget Training Hierarchy

Budget
Mastery

Budget Building

Budget Categories

Funding Source

Direct & Indirect Costs

Today's Goals!

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

Our Budget Training Hierarchy

Budget
Mastery

Budget Building

Budget Categories

Funding Source

Direct & Indirect Costs

Today's Goals!

What do you think the major budget categories are?

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- 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

*NOT an exhaustive list

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Let's Dive In!

- 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							
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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.

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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
- **Subawards**: Money that will go to another institution. The sub-awardee is a scientific partner who will contribute to decision making.

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Total Direct Consortium Costs				Direct	\$225,000
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Indirect Cost RATE

- **Direct Costs**: 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

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Determining your Indirect Cost

- **Direct Costs**: 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.
1. Add all direct costs
 2. Subtract all excluded 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!

Put Me in Coach!

1. Add all your site's (BMC) direct costs
2. Subtract all excluded 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?

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Total Personnel Costs				\$79,930		\$24,723 \$104,653
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Travel Costs		Rate		Trips		Total
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Modified Total Direct Costs						
Indirect Costs (78%)						
Total Costs						

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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

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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
						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 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

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

Not allocating
enough staff
time

Salary caps

Budgeting Pitfalls

Budget caps

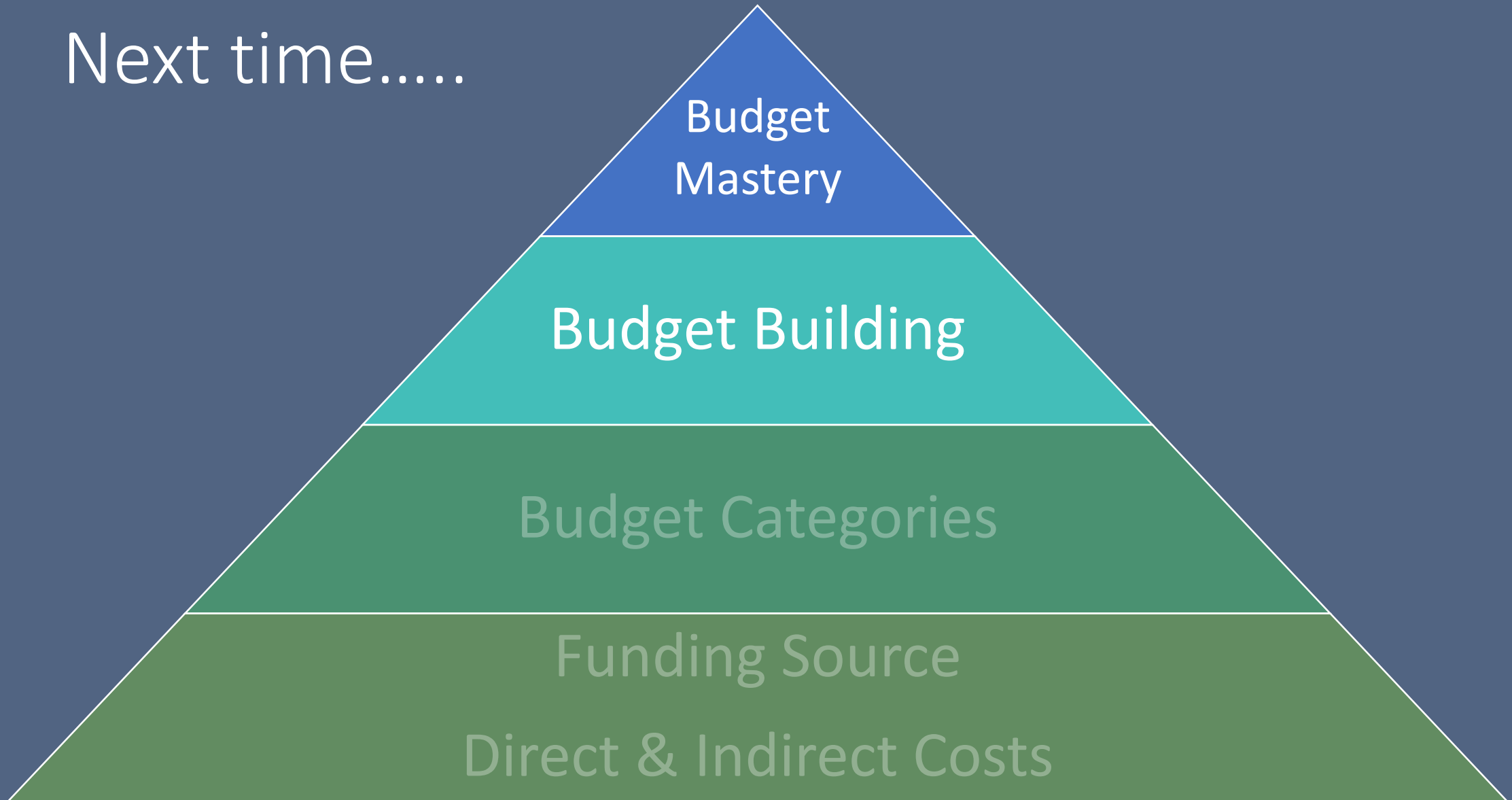
Missing
information
needed to
determine costs

Underestimating
time

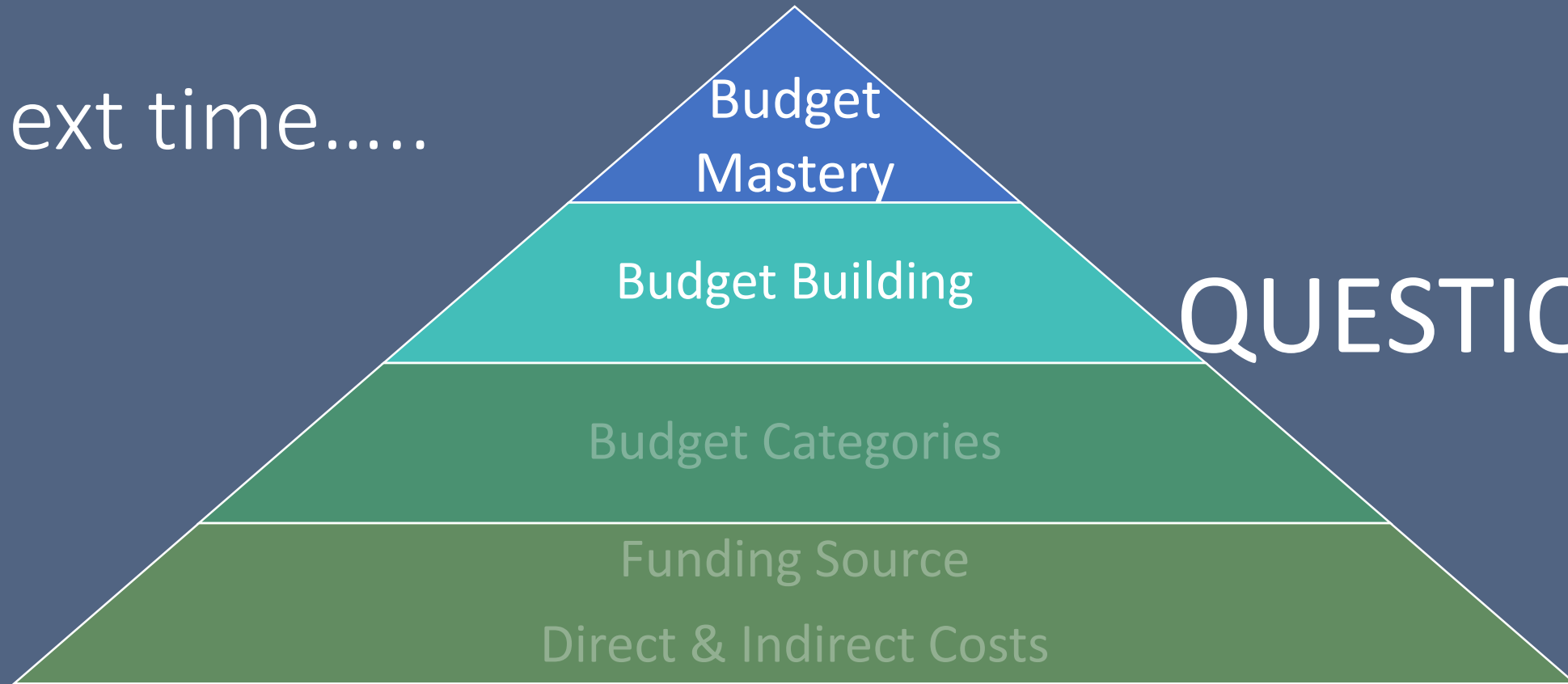
Not
planning for
attrition

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

Next time.....



Next time.....



QUESTIONS!

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-Finance/cost_accounting/Typical_Direct_and_Indirect_Costs.pdf

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/
BMC	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