

STUDY BUDGET DEVELOPMENT

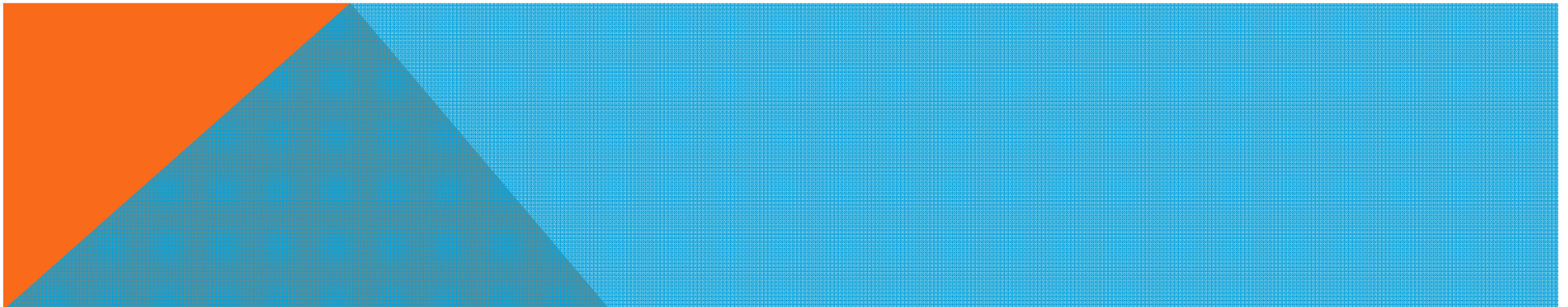
Presented by

Phyllis Klein, RN, CCRC, BSN

Director, Regulatory Compliance & Support
Center for Clinical Studies

Washington University in St. Louis

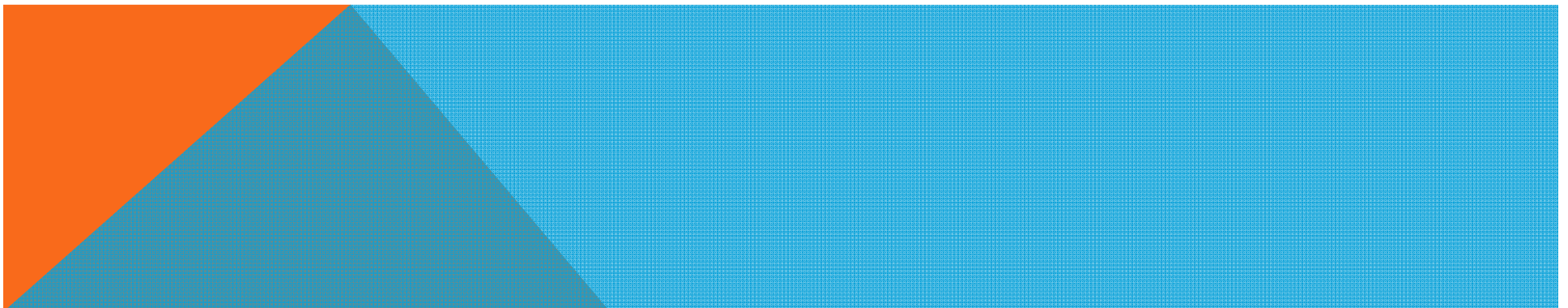
(314) 747-4289



OBJECTIVES

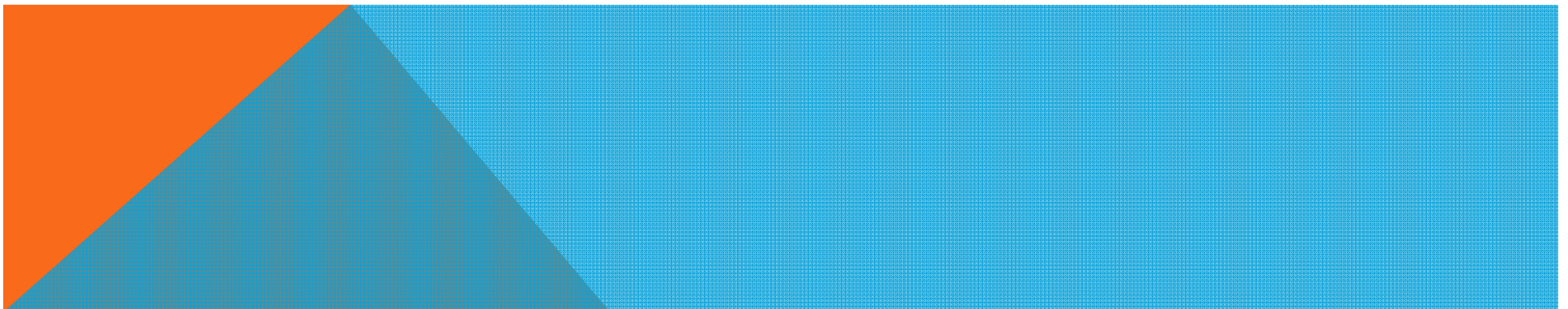
▶ To understand:

- ▶ How to get started when creating a budget
- ▶ What items to include in your budget
- ▶ Why your study should not bill two sources for the same procedure
- ▶ Why patients should not get billed for something the study should provide for free
- ▶ Making sure all the paperwork says the same thing



PURPOSE:

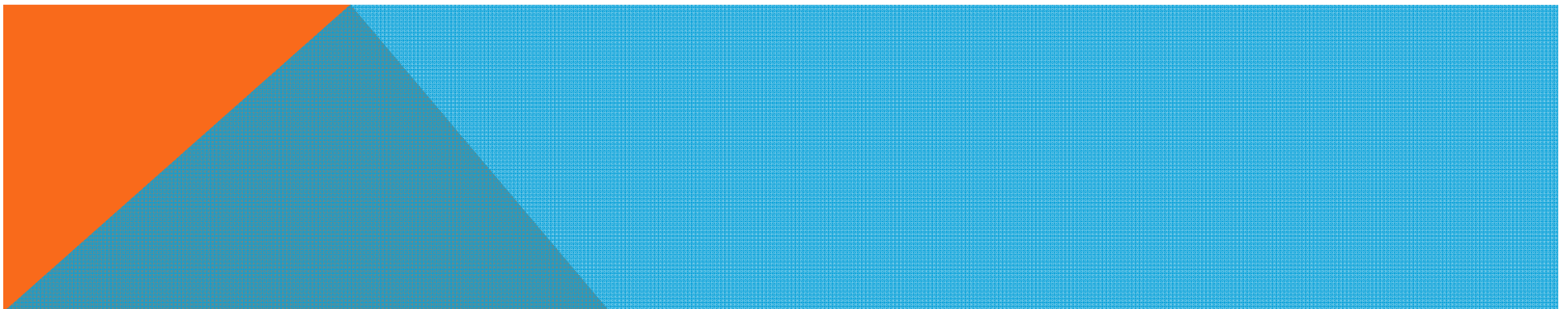
- You need an independent review of local costs
- An opportunity to compare costs, and see if the sponsor's offered budget is adequate
- To assess whether the study is right for you based on not only reimbursement factors, but outcomes.
- Is this study right for your patient population?
- Is there an open-label follow-up study for a drug study involving a new product



STUDY START-UP FEES...

Start-up fees are supposed to cover the effort to prepare for the study before the first patient walks through the door:

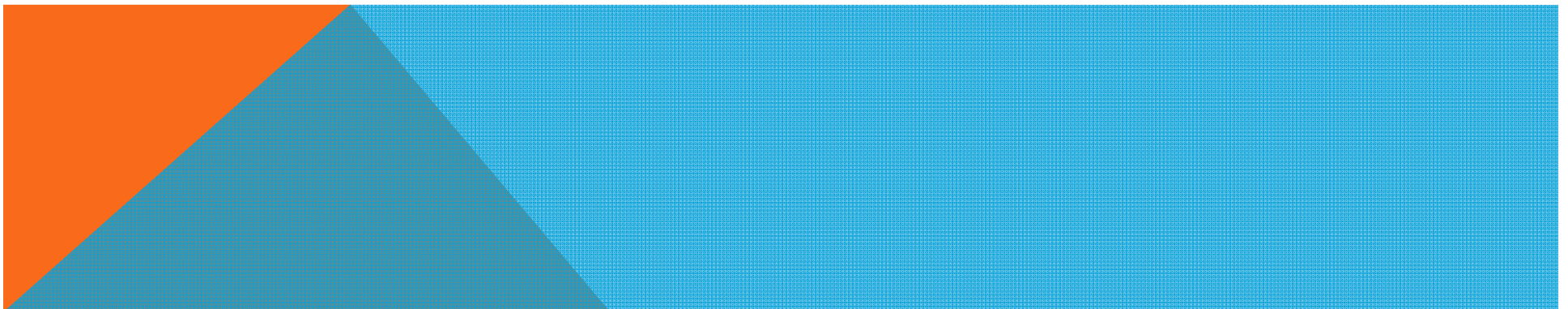
- Budget preparation & negotiations
- Contract language negotiations
- Coordinator set-up of source docs, CRF training, unpack lab kits, set-up lab/radiology accounts, etc.
- IRB review preparation
- Regulatory document preparation for the sponsor



PER PATIENT STUDY BUDGET...

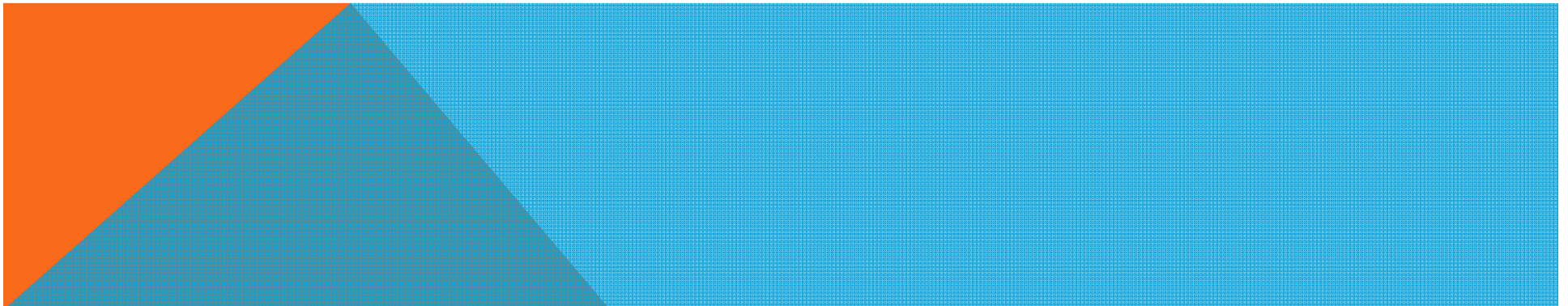
The '*per patient*' budget generates funds to pay for:

- Coordinator fees
- PI fees
- Procedure costs
- Facility fees
- Labs



COMPUTING YOUR HOURLY RATE

	<u>hours/year</u>
Full time employee (works 261 days/year)	<u>2,080</u>
Less hours/vacation (22 days)=	- 176
Less unverified sick time (5 days)=	- 40
Less paid holidays (8 days)=	<u>- 64</u>
Actual workable hours /year	<u>1,800</u>
Less breaks, e-mail, etc.@1 hr per work day=	<u>-225</u>
Yielding realistic work hours/year	<u>1575</u>
Less mandatory training, meetings, ~hrs/yr =	-52
Less inefficiencies (times when work is slow)=	<u>????</u>
Approximate possible billable hours/year	1523



YOUR HOURLY RATE

Take the annual salary of the employee

Add ~30% for all benefits (if academia)-you need to know the approximate percentage your company uses

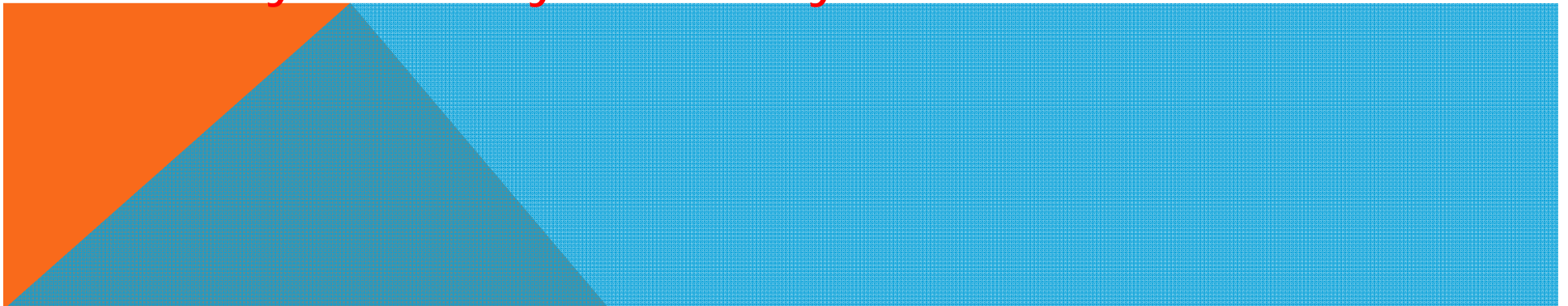
Divide by 1523 realistic workable hours

For instance:

- \$60,000 annual salary
- Plus 30% (benefits) or \$ 18,000=\$78,000
- **Divide by 1523 hours=\$51.21 per hour**

(This # does not allow for inefficiencies when work is slow)

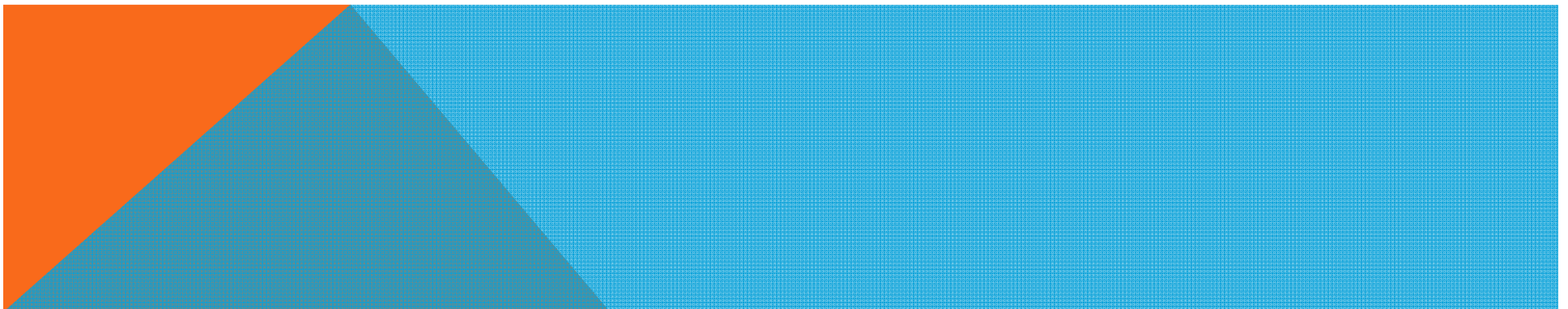
Now, you have your hourly rate!



GETTING STARTED

Now that you have your hourly rate, you are ready to start!

- Print out the schedule of events
- Read the protocol – in detail...takes notes on the schedule
- Determine what services for which you need to obtain pricing (e.g. x-rays, MRIs, RHC, biopsies; scopes, etc.)
- Are any of these services considered standard of care (SOC)?
- Identify those that are needed for the research only – your budget should only include research services.



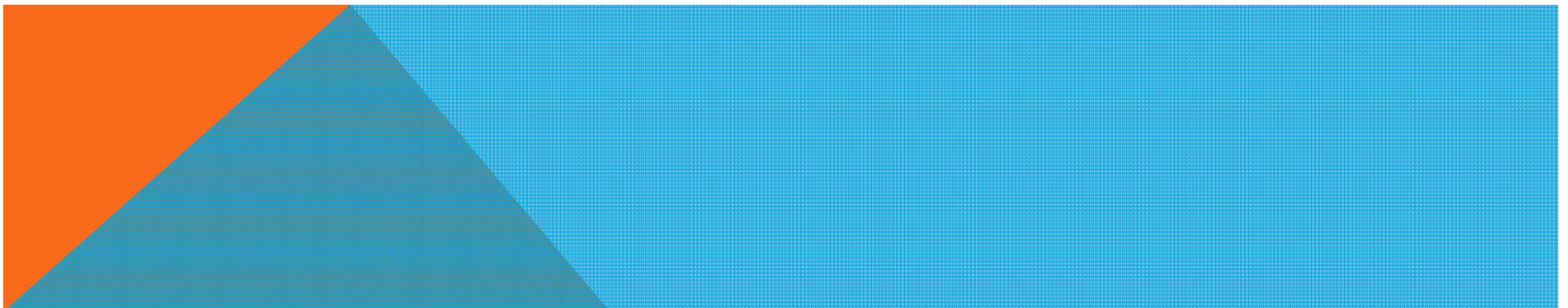
SCHEDULE OF EVENTS

Compare the schedule of events with the protocol requirements

Note: The protocol does not always match the grid!

Determine *how long* you will need to be with the patient at each visit.

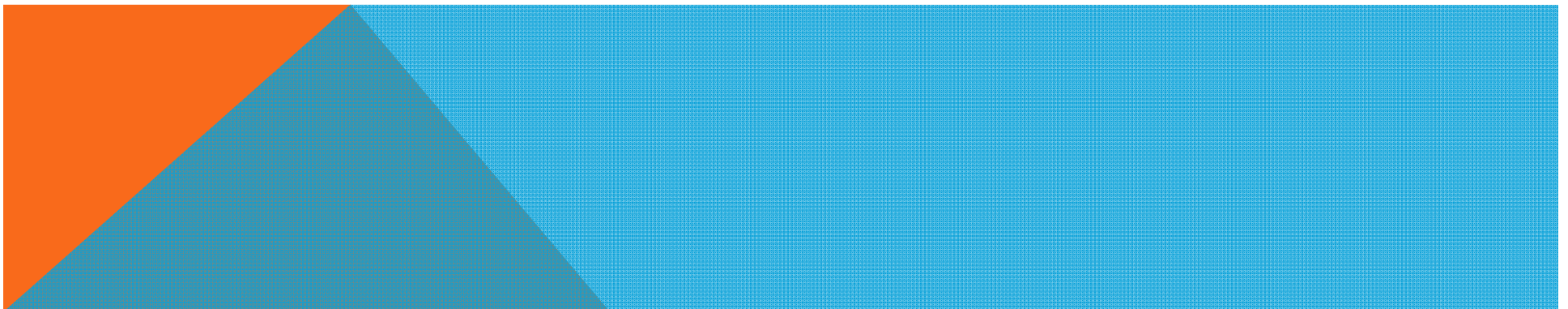
- Is there time needed to set up before the patient arrives?
- What paperwork needs to be done when the patient leaves?



HOW MUCH TIME DOES IT TAKE?

Affix a cost for each study-related procedure based on who is involved and the time it takes. Use your hourly rate.

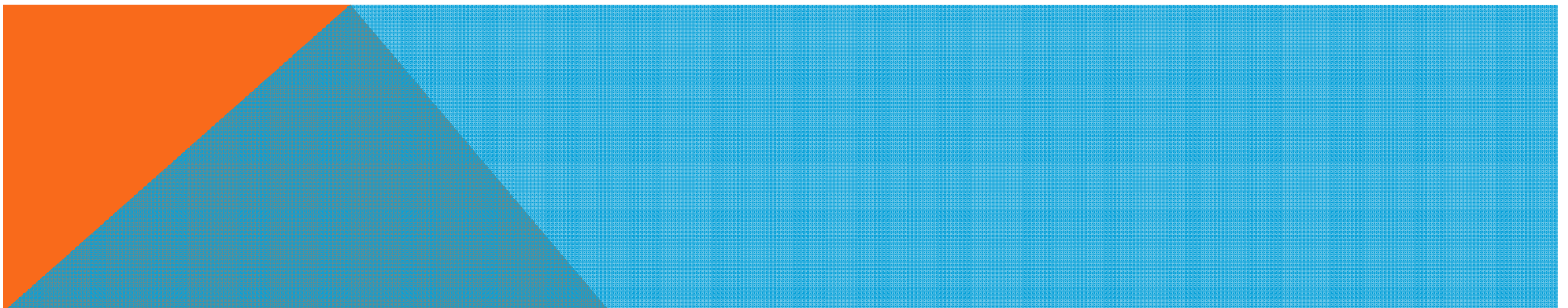
Obtain a price quote with a research discount for those procedures done by others (facility and professional fees)



PATIENT REIMBURSEMENTS

Will patient reimbursements be a factor in your budget?

- Patient stipends / Greenphire?
- Parking fees
- Mileage
 - business rate is \$.54 per mile for 2016
 - medical rate is \$.19 per mile for 2016
- Taxi's fees
- Hotel charges





Budget By Visit

Event		Visit	1	2	3	4	5	6	7	8	9	Total
		Screening	Baseline - D1	Week 2	Week 4	Week 8	Week 12	Week 16	Week 20	Follow-up- 4 Weeks following last dose		
Administrative	Patient Stipend 2	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00		\$504.00
	Parking	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60		\$100.80
	CTU Facility fee	\$37.80	\$37.80	\$37.80	\$37.80	\$37.80	\$37.80	\$37.80	\$37.80	\$37.80		\$302.40
	Dry Ice	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60	\$12.60		\$100.80
Coordinator Services	Informed consent	\$94.50										\$94.50
	Inclusion/Exclusion Criteria	\$94.50	\$94.50									\$189.00
	Demographics	\$25.20										\$25.20
	Medical History for study	\$94.50										\$94.50
	Con Med review	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20		\$201.60
	Phlebotomy	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40		\$403.20
	Lab Processing	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40		\$403.20
	Urine Specimen Collection	\$25.20		\$25.20		\$25.20		\$25.20				\$100.80
	Medication Dispensing-CRC		\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20				\$151.20
	Healthcare Resource Utilization	\$25.20								\$25.20		\$50.40
	Questionnaires	\$25.20				\$25.20			\$25.20			\$75.60
	CRF Completion	\$189.00	\$189.00	\$94.50	\$94.50	\$94.50	\$94.50	\$94.50	\$94.50	\$94.50		\$945.00
	Monitoring visit	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40		\$403.20
	Telephone Follow-up										\$94.50	\$94.50
EVALUATION & MANAGEMENT	Physical Exam	\$189.00										\$189.00
MEDICINE	EKG	\$126.00										\$126.00
PHARMACY	Med Prep & Dispense fee-oral med		\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20				\$151.20
Total Budget Including Overhead (26%)		\$1,190.70	\$636.30	\$472.50	\$447.30	\$497.70	\$447.30	\$472.50	\$447.30	\$94.50		\$4,706.10



Budget Cost Summary

Event	Cost	OH	Cost + OH	Qty	Cost Per Patient	Enrollment Target	Total Costs
Administrative							
CTU Facility fee	\$15.00	26.00%	\$18.90	16	\$302.40	10	\$3,024.00
Dry Ice	\$10.00	26.00%	\$12.60	8	\$100.80	10	\$1,008.00
Parking	\$10.00	26.00%	\$12.60	8	\$100.80	10	\$1,008.00
Patient Stipend 2	\$50.00	26.00%	\$63.00	8	\$504.00	10	\$5,040.00
	85.00		\$107.10	40	\$1,008.00		\$10,080.00
Coordinator Services							
Con Med review	\$20.00	26.00%	\$25.20	8	\$201.60	10	\$2,016.00
CRF Completion	\$75.00	26.00%	\$94.50	10	\$945.00	10	\$9,450.00
Demographics	\$20.00	26.00%	\$25.20	1	\$25.20	10	\$252.00
Healthcare Resource Utilization	\$20.00	26.00%	\$25.20	2	\$50.40	10	\$504.00
Inclusion/Exclusion Criteria	\$75.00	26.00%	\$94.50	2	\$189.00	10	\$1,890.00
Informed consent	\$75.00	26.00%	\$94.50	1	\$94.50	10	\$945.00
Lab Processing	\$40.00	26.00%	\$50.40	8	\$403.20	10	\$4,032.00
Medical History for study	\$75.00	26.00%	\$94.50	1	\$94.50	10	\$945.00
Medication Dispensing-CRC	\$20.00	26.00%	\$25.20	6	\$151.20	10	\$1,512.00
Monitoring visit	\$40.00	26.00%	\$50.40	8	\$403.20	10	\$4,032.00
Phlebotomy	\$40.00	26.00%	\$50.40	8	\$403.20	10	\$4,032.00
Questionnaires	\$20.00	26.00%	\$25.20	3	\$75.60	10	\$756.00
Telephone Follow-up	\$75.00	26.00%	\$94.50	1	\$94.50	10	\$945.00
Urine Specimen Collection	\$20.00	26.00%	\$25.20	4	\$100.80	10	\$1,008.00
	615.00		\$774.90	63	\$3,231.90		\$32,319.00
EVALUATION & MANAGEMENT							



Budget Cost Summary

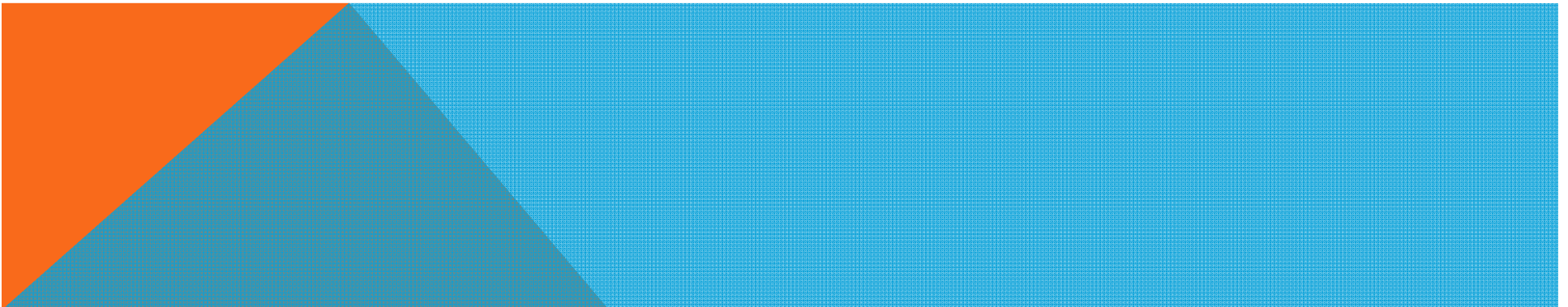
Event	Cost	OH	Cost + OH	Qty	Cost Per Patient	Enrollment Target	Total Costs
Physical Exam	\$150.00	26.00%	\$189.00	1	\$189.00	10	\$1,890.00
	150.00		\$189.00	1	\$189.00		\$1,890.00
MEDICINE							
EKG	\$100.00	26.00%	\$126.00	1	\$126.00	10	\$1,260.00
	100.00		\$126.00	1	\$126.00		\$1,260.00
PHARMACY							
Med Prep & Dispense fee-oral med	\$20.00	26.00%	\$25.20	6	\$151.20	10	\$1,512.00
	20.00		\$25.20	6	\$151.20		\$1,512.00
Total Costs	970.00		\$1,222.20	111	\$4,706.10		\$47,061.00

START-UP FEES/INVOICED ITEMS

Don't forget your initial & annual costs

- IRB submission fees
- IRB Preparation/Regulatory fees
- Research Pharmacy fees
- Document Archiving Storage fee

On all amounts in your study budget—
add OVERHEAD!





Budget Startup Costs

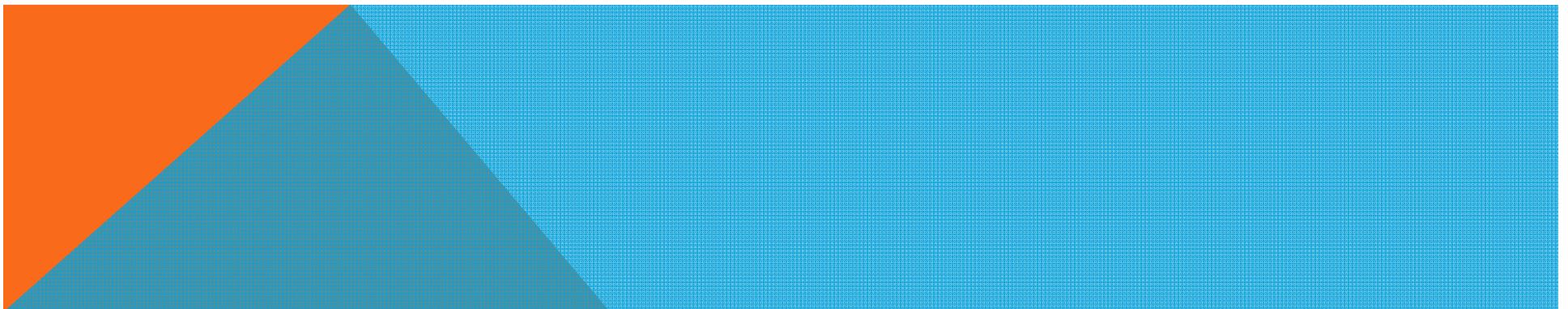
Event	Initial Fees	Annual Fees	PRN Items	Comments
Start-up Costs & Invoiced Items				
IRB Initial Review Fee	\$3,150.00			
IRB Annual Review fee		\$1,890.00		
Negotiation of changes to WU ICF injury language			\$630.00	
Regulatory & Initial IRB Preparation Fee	\$3,500.00			
Annual Regulatory & Preparation fee		\$1,000.00		
Amendment Processing fee			\$500.00	
Coordinator Start-up Fee	\$2,500.00			
Research Pharmacy Initial fee	\$1,225.00			
Research Pharmacy Annual fee		\$1,000.00		
Document Archiving	\$1,000.00			
Advertisement & Recruitment	\$5,000.00			
Pre-Screening Funds	\$2,000.00			
Screen failures			\$1,190.70	
SAE at our site			\$700.00	
Review/Submission of IND safety reports			\$25.00	
Re-consenting due to ICF change			\$75.00	
	18,375.00	\$3,890.00	\$3,120.70	
Total Costs	18,375.00	\$3,890.00	\$3,120.70	

PRE-SCREENING TIME

Industry sponsors do not always want to cover the cost of pre-screening of potential patients

- Include time in your screening visit
- Ask for a Start-Up fee to cover this effort
 - Pre-screening fee
 - Recruitment/Advertising fee

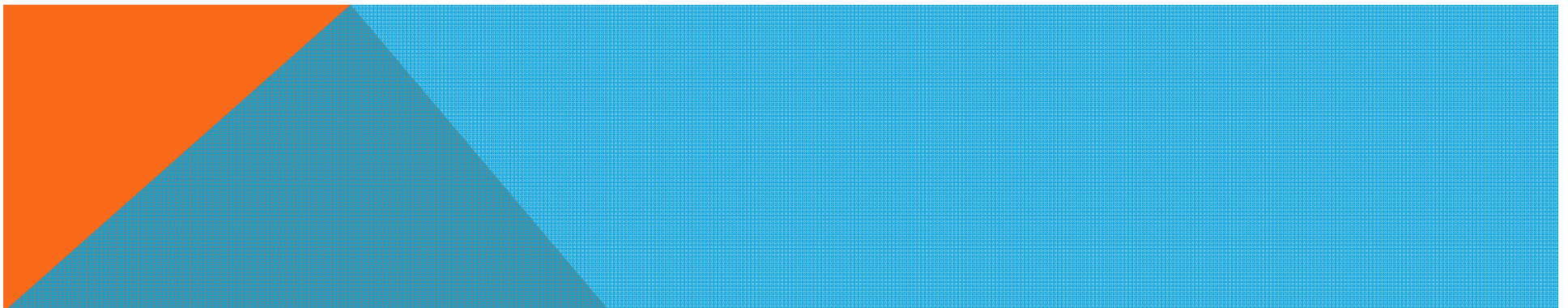
NIH format of providing an FTE covers this effort



EXAMPLES OF FEES

These are examples of fees we try to recover in the budgets we negotiate for effort in preparing for study start-up:

- Initial IRB Prep & Regulatory \$ 3,500
- Annual IRB Prep & Regulatory \$ 1,000
- Amendment Prep & Processing \$ 700 each
- Coordinator Start-Up \$ 2,500
- Investigator Feasibility & Review \$ 1,000



MORE FEES...

Med Storage (locked cabinet) \$500-\$1000

Research Pharmacy costs

(not needed if you store/dispense yourself)

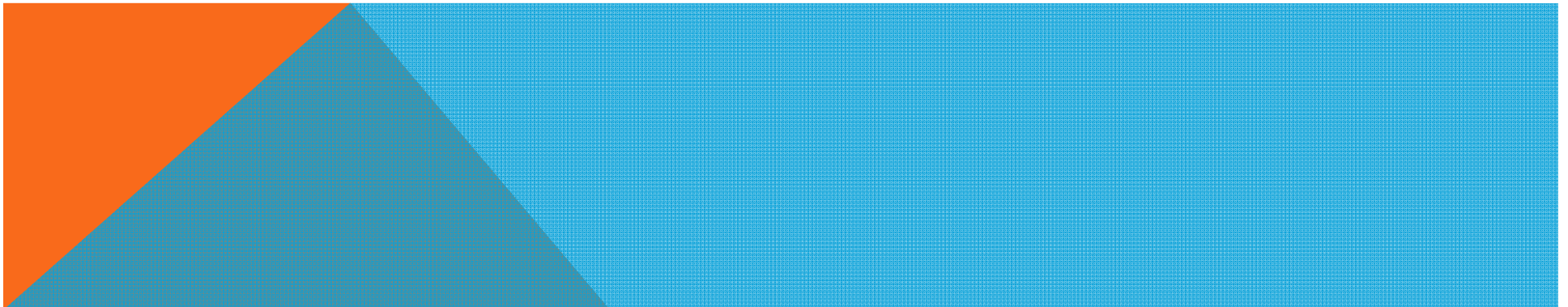
▪ (Initial and annual fees + OH) \$1500 - \$700

Advertising/Recruitment \$5,000 or

Pre-screening funds (charts) \$2,000

Document Archiving \$1,000

▪ Remember, it's for up to 15 years



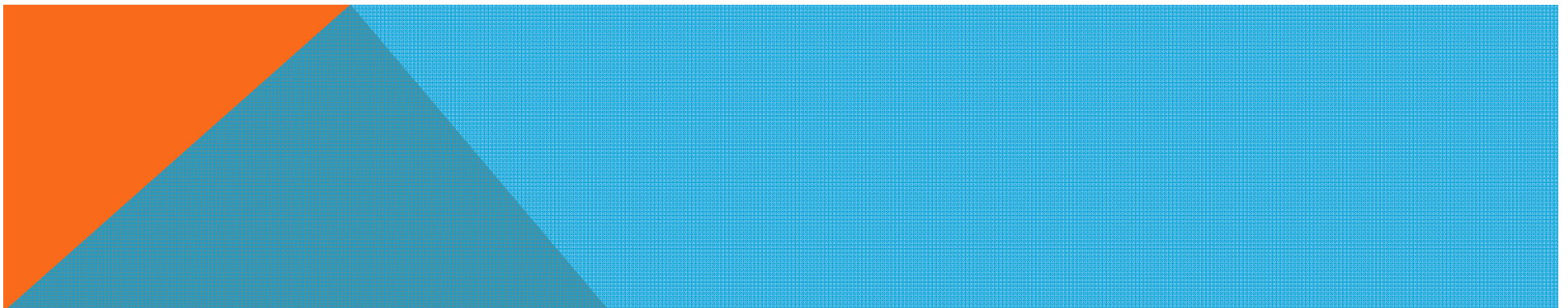
COVERING YOUR COSTS...

Patient Stipend – sponsor's amt	\$ 50
Parking fees	\$ 15 day
CRF Completion/SM	\$ 75/hr

- (Your cost plus extra for unexpected events)

Be sure to include enough hours for the coordinator.

- Sometimes the paperwork may take 2 hours per patient visit. Sometimes, there is an hour before the visit to consider, too!
- Local labs or Central lab?



BE ABLE TO JUSTIFY YOUR COSTS

Consenting & documenting I/E

Phlebotomy – \$60-\$75/hour RN or \$30-\$35/med tech

- ½ hour

Lab Processing - \$60-\$75/hour RN or \$30-\$35/med tech

- ½ hour or more

Vital signs

Height – Weight

Con med review



(Refer to the hourly amount you calculated)

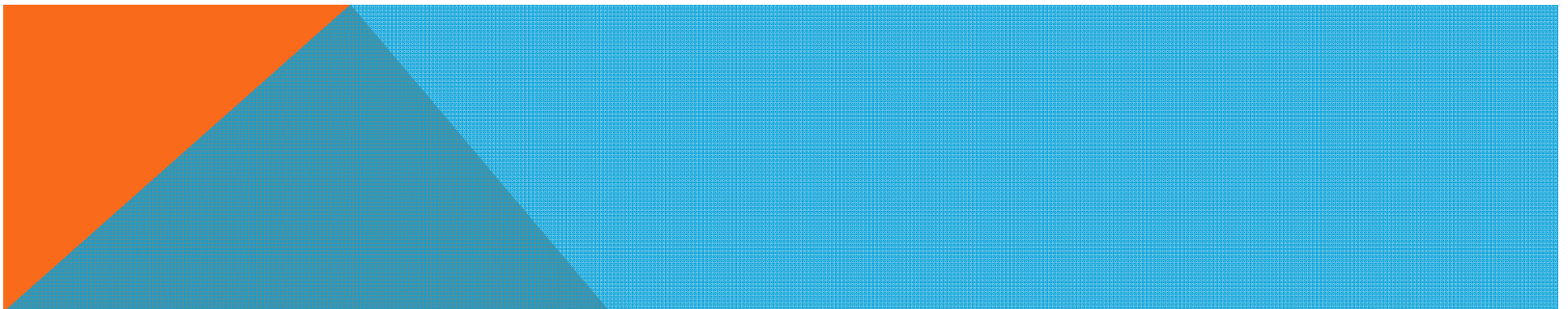
MEDICATION PREP...

Medication dispensing - Who is doing it? Pharmacy or coordinator or both?

Med accountability - Is this the pharmacy's responsibility or the coordinators?

Are there prophylactic meds that need to be dispensed?

Is this a device that needs prophylactic meds administered?

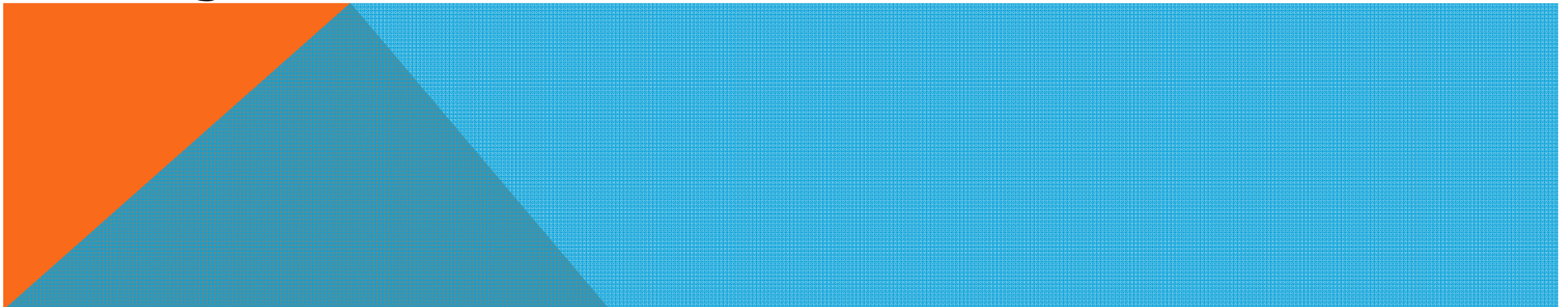


SOMETHING TO THINK ABOUT

When figuring the fee to do an infusion or ECG, remember the costs of equipment maintenance (calibrations)...these *expenses* should be included in the cost of the procedure:

For example, we allow:

- IV Pump use & supplies, per infusion \$25
- EKG machine \$25
- So if the infusion takes 1 hour @ \$75 then the charge per infusion should be \$100 (\$75 nurse + \$25 pump) OR have a small fee for supplies in the administrative portion of your budget.



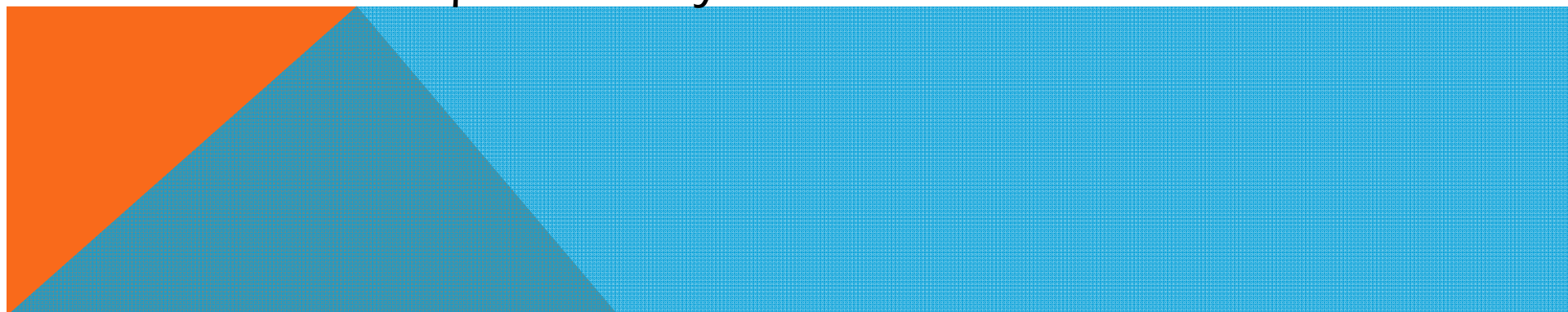
COVERING YOUR COSTS

Monitoring Visits (with Sponsor's rep)

@\$60-\$75/hour – add ~ ½ hour per patient visit (*e.g.*
\$35-\$40 per visit)

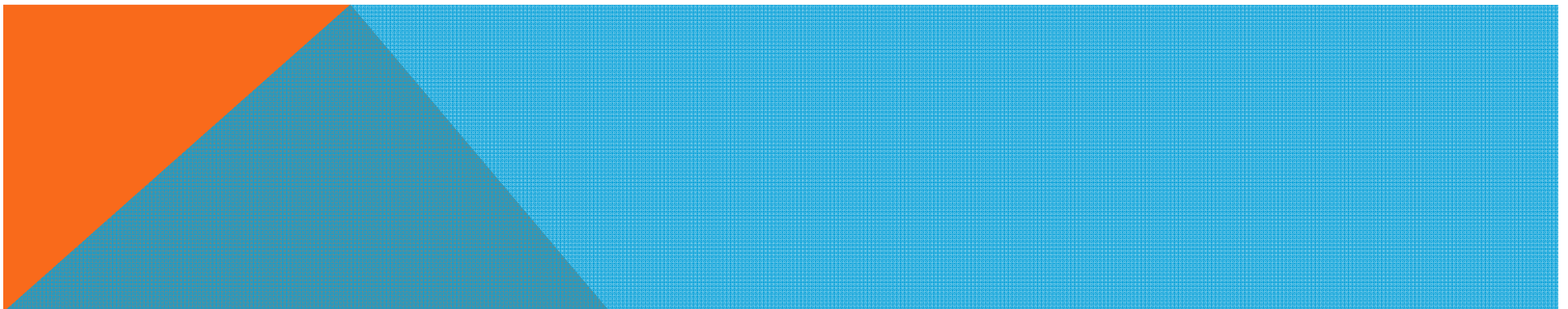
Sponsors will tell you that these expenses are part of the cost of doing business, but you need to account for this somewhere!

Usually when monitors come, they monitor more than one chart/visit– so the ½ hours you add-in will add-up to cover your time overall



PI FEES

- PI fee –We figure \$50 per study visit /per patient unless PI specifies something different (to oversee study)
- If in doubt, ask your principal investigators what amounts they would like to include
- This fee covers their time to sign off on paperwork and meet with coordinator weekly.



HOURLY FEES

Regulatory/Coordinator work, by the hour,
\$60-\$75/hour (depends on the salary of the employee)

CHART REVIEW, by the chart, \$35 per patient (FYI: ratio
of 3 screened to each enrolled)



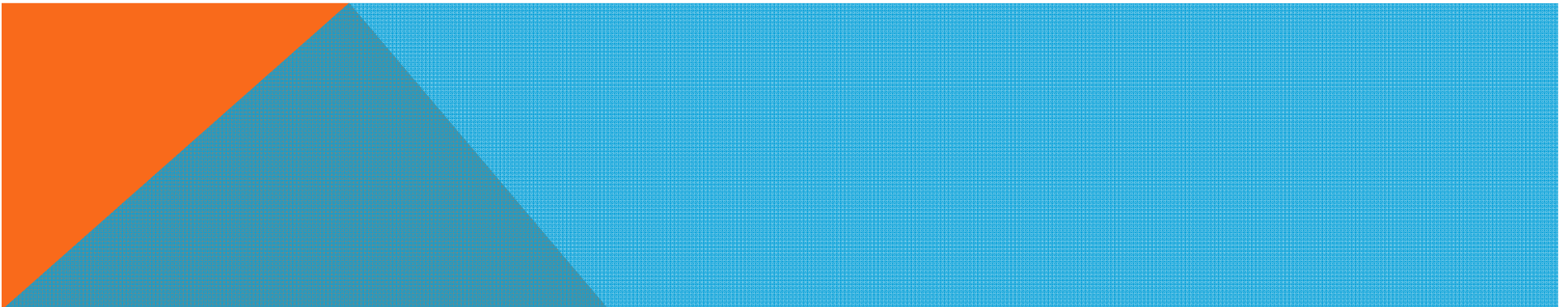
NEGOTIATIONS

Industry sponsor's usually have a little wiggle room on their budgets...

It used to be about 30% before they need approval from the next level up.

With the cost cuts, the Sunshine Act, and fair market value, it is now less

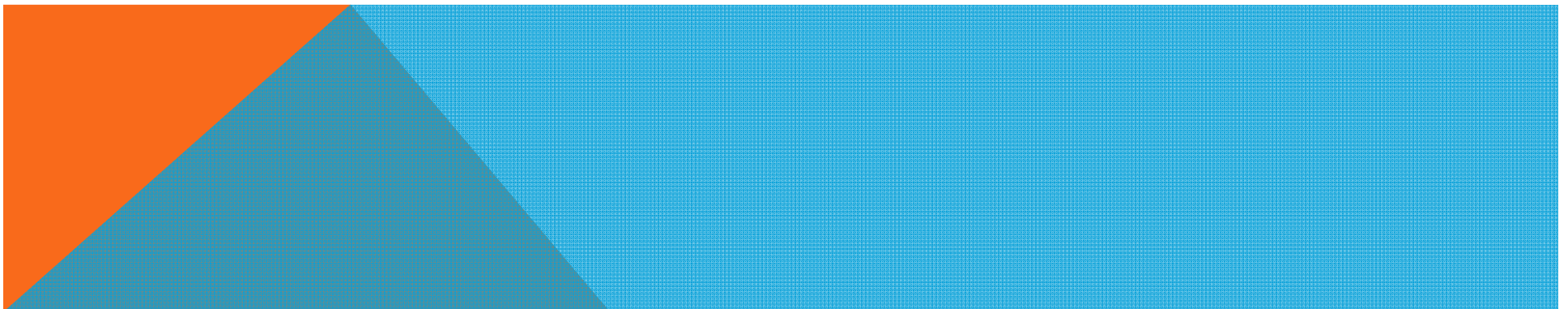
Don't be afraid to ask for what you need, all they can say is no!



BUDGET AT YOUR COST...

These studies need to be budgeted at your *cost*:

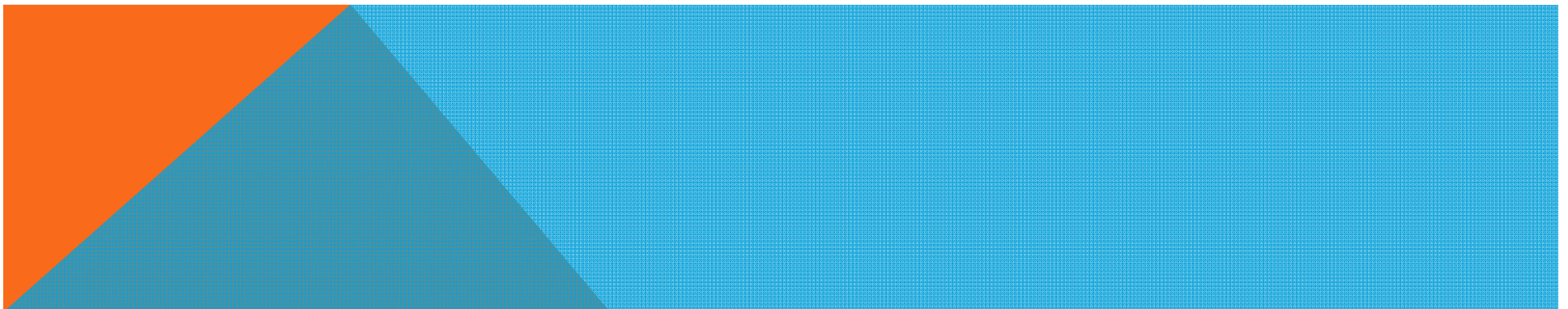
- Any studies funded by:
 - NIH
 - Collaborative Groups funded by NIH
 - Department of Defense
 - Center for Disease Control



FEDERALLY FUNDED STUDIES: WHAT IS COST?

For labor: it is the salary plus benefits for an employee—many times you name the employee

If this is the case, you will budget for an FTE (full time equivalent) of an individual's salary

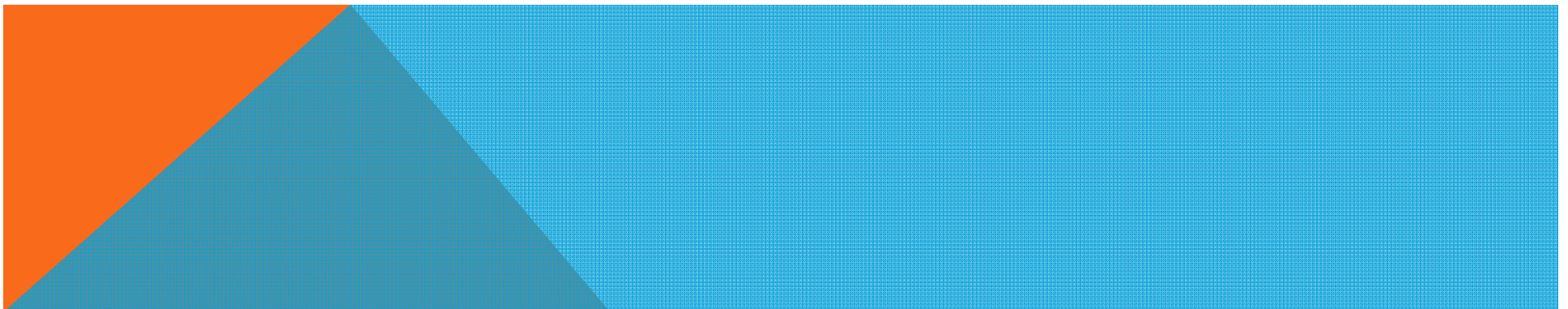


DETERMINING COSTS: PROCEDURES & SUPPLIES

Many times, there are two different rates for procedures -
industry & federal

When requesting costs for a *federally* funded study, tell your
contact that the study is federally funded so that they can
provide you with the correct price quote.

This applies to quotes for labs, x-rays, hospital procedures,
room rates, etc.



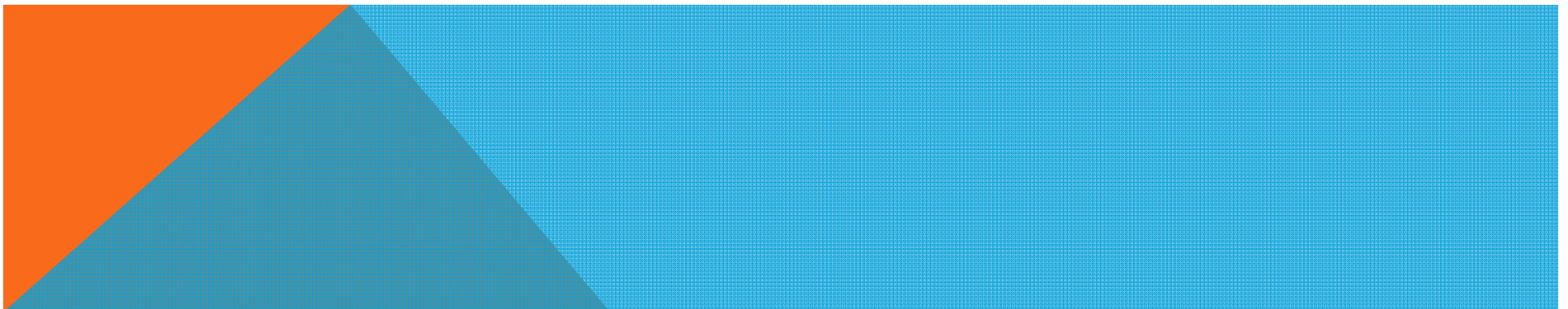
OVERHEAD

The overhead rate for federally funded studies may vary depending on the study

- You will need to find out the overhead rate from the group that typically handles your grants (our rates is 54%)

The overhead rate for industry sponsored studies at WU is :

- 26% dean's overhead
- +5-11% department overhead, if applicable



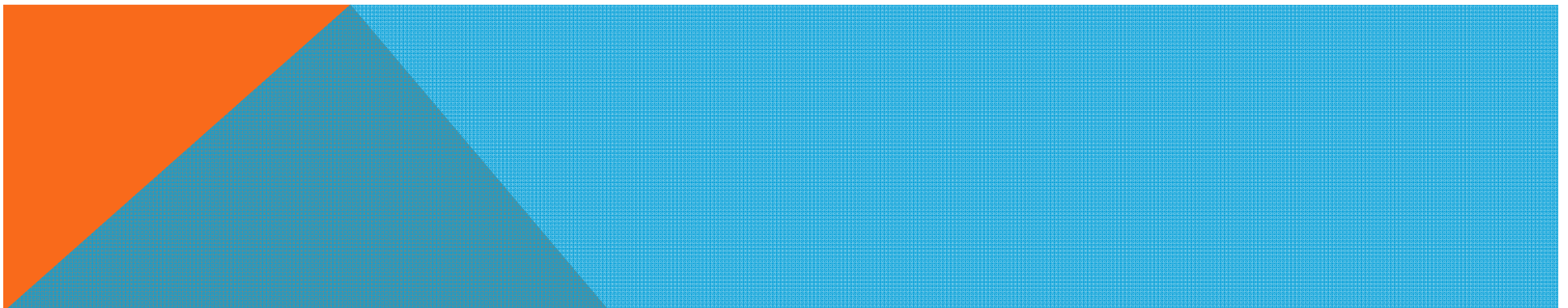
PATIENT COSTS – WU OPINION

Patients are responsible for any co-pays or deductibles that are part of their insurance plan if the procedure is billed to insurance.

We CANNOT reimburse the cost of the co-pays or deductibles even if the study sponsor wants to provide this funding for us.

It could be construed as a violation of the federal anti-kickback statute for the healthcare provider to waive the patient's co-pays/ deductibles, and viewed as an inducement or coercion for the patient to participate.

If covered by the study budget, you MUST pay for the entire procedure from the study funds—you cannot allow the patient/insurance company or Medicare to cover even part of the cost.



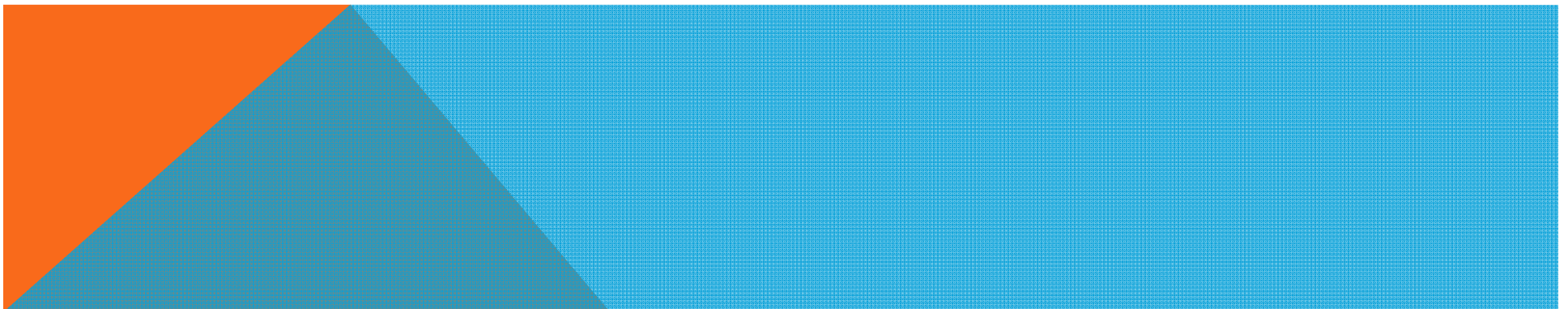
MIXING RESEARCH WITH ROUTINE CARE

Benefits:

- Streamline patient care
- Lower costs 'per patient' for sponsor

Issues:

- Risk that patient insurance will be denied if their healthcare insurance policy does not include research participation
- Potential for billing errors (double billing)
- More coordinator time to protect patient
- More administrative time to correct billing errors



SOC VERSUS INVESTIGATIONAL

Charges covered in your study budget *cannot* be billed to another source – *double-dipping* is illegal!

If standard care dictates, and the procedure will be paid by patient insurance or Medicare, then you *cannot* have the cost in your study budget

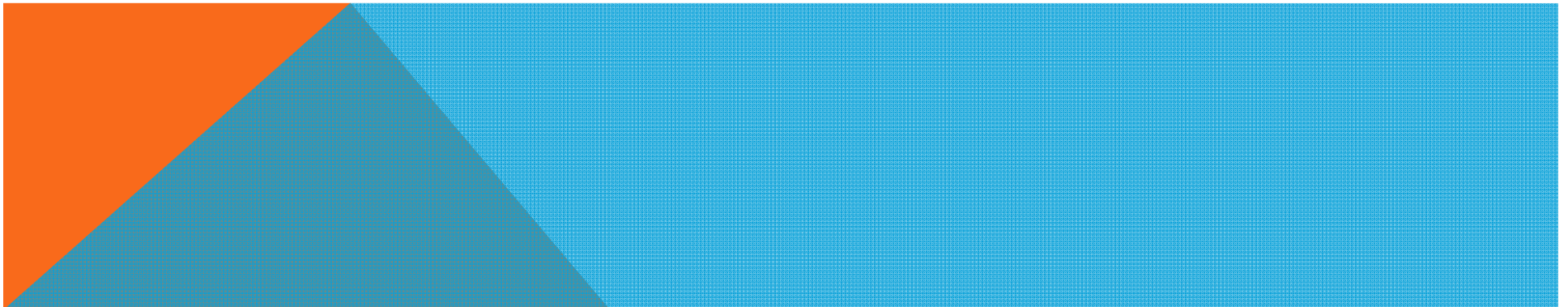
If the informed consent says the patient will not pay for certain services, then they *cannot* be charged, and neither can their insurance company or Medicare – if promised free, it's free! Make sure the ICF is in parity with the budget!



WU BILLING COMPLIANCE RULES

Insurance Denial Language

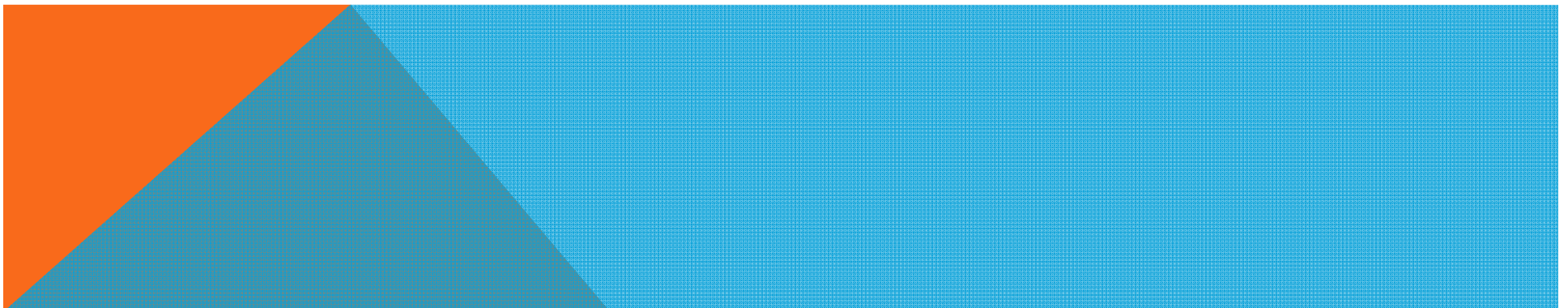
- Most-favored-nation type rule: another payor cannot be treated better or given a better deal than Medicare is given
- Medicare is always secondary payor (MSP rule)
- If Medicare has agreed to cover the cost of a device or procedure, but a health insurance provider denies coverage and the sponsor pays the bill...guess what? - the Medicare patient will also then get the procedure paid for by the sponsor



PRE-CERTIFY PATIENTS FOR INSURANCE COVERAGE

Since not all insurance plans cover patients participation in research, if your study involves any routine coverage (insurance billing), it is helpful to know if the patient's insurance will allow their participation.

If the answer is 'no', then the study must pay for everything, or the patient must not participate. It wouldn't be fair to burden your patient with medical bills that could have been avoided.



STUDY BUDGET DEVELOPMENT

- **Questions ?**
 - If you have questions, there is a mechanism in place for them to get to me.
 - I will answer them via e-mail
 - Thank You!

