



Office of Clinical Research First Friday

 **Health**™ IN SCIENCE LIVES HOPE.

**Budgeting for
Federally Funded
Research**

Friday, April 2nd, 2021

Learning Objectives:

- 1) Identify the basic elements of a federal sponsored program budget.
- 2) Distinguish the unique elements of a federal clinical research budget.
- 3) Discuss the invoicing process for a federal clinical trial.

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

Off-Label Disclosure Statement:

Faculty members are required to inform the audience when they are discussing off-label, unapproved uses of devices and drugs. Physicians should consult full prescribing information before using any product mentioned during this educational activity.

Learner Assurance Statement

The University of Cincinnati is committed to resolving all conflicts of interest issues that could arise as a result of prospective faculty members' significant relationships with drug or device manufacturer(s). The University of Cincinnati is committed to retaining only those speakers with financial interests that can be reconciled with the goals and educational integrity of the CME activity.

Accreditation Statement for Directly Sponsored Activity

The University of Cincinnati is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Cincinnati designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit*™. Participants should claim only the credit commensurate with the extent of their participation in the activity.

CRPs, NPs, PAs, and RNs can count activities certified for *AMA PRA Category 1 credit*™ for professional credit reporting purposes. Other healthcare professionals should inquire with their certifying or licensing boards.

Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

Speaker Disclosure:

In accordance with the ACCME Standards for Commercial Support of CME, the speakers for this course have been asked to disclose to participants the existence of any financial interest and/or relationship(s) (e.g., paid speaker, employee, paid consultant on a board and/or committee for a commercial company) that would potentially affect the objectivity of his/her presentation or whose products or services may be mentioned during their presentation. The following disclosures were made:

Planning Committee Members:

- Brett Kissela, MD, Course Director – No Relevant Relationships
- Maria Stivers, MS – No Relevant Relationships
- Zachary Johnson, BS – No Relevant Relationships
- Nate Harris, BS, Course Coordinator – No Relevant Relationships
- Brandon Armstrong, CME Program Coordinator – No Relevant Relationships

Speakers:**Kelly Niederhausen**

Assistant Director of Research & Education
Department of Internal Medicine
Sr. Business Administrator
Division of Infectious Diseases
No Relevant Relationships

Lisa Schira

Business Manager
Division Of Infectious Diseases
Internal Medicine Academic Research Services
Office of Medical Education
University of Cincinnati
No Relevant Relationships

Patrick Clark

Associate Vice President, Operations and Business Intelligence
Office of Research
University of Cincinnati
No Relevant Relationships

April 2021 Study of the Month

Atopic Dermatitis Research Study

Do you have itching due to Atopic Dermatitis (Eczema)?

What

The purpose of this clinical research study is to evaluate whether an investigational medicine can help reduce itching in people with Atopic Dermatitis, commonly known as eczema.

Who

People at least 12 years old who have had Moderate-to-Severe Atopic Dermatitis for at least 2 years.

Pay

Participants will be compensated for their time and travel.

Details

For more information, call (513) 475-7631 or call (513) 558-0951.



24-20 IRB # 2019-0829



Compliance Corner

Updating Active PIs and Coordinators in EPIC:

If any personnel changes occur on an active study in EPIC, research coordinators and PIs must be manually updated in the EPIC Research Record in production.

If the active research staff on a study is not updated in EPIC, the active staff could potentially miss important automated alerts, such as:

- Appointment Change/Update Alerts
- ADT Alerts

Research staff, PIs and Coordinators, are updated via the Research Study Maintenance Activity

Related:

Epic Research Alerts (In Basket Messages or Pager Alerts) are occasionally built to send notifications to individuals. When study staff (PIs / Coordinators) are changed/updated- the new study staff should confirm with the outgoing staff member if there are any Epic Alerts that are set to be sent to Individuals

If alerts are being sent to research staff individuals that are no longer active on the study, EPIC IT would need to be notified to update the alert recipient.



Thursday, April 15th, 2021
12:00 noon - 1:00 pm
Virtual Presentation

ResearchMatch and other Recruitment Services

Please join us for an overview of ResearchMatch, a free and secure online recruitment tool that helps match willing volunteers with eligible studies at institutions nationwide, and other recruitment services offered by the OCR. Join us to learn more!

Miranda Gulasy

Clinical Research Recruitment and Sponsor Relationship Administrator
ResearchMatch Liaison
UC Health Office of Clinical Research

Today's Presentation:

**Budgeting for Federally Funded
Research and Clinical Trials**

Kelly Niederhausen

Lisa Schira

Patrick Clark

University of Cincinnati

Budgeting Basics

- Work with your Department / College BA / GA / AOR
 - College of Medicine AORs:
 - Kim Kues, kim.kues@uc.edu 513-558-5078
 - Steve Manning, steven.manning@uc.edu 513-558-2045
 - Teresa Larkin, teresa.larkin@uc.edu 513-558-3551

Budgeting Basics

- Budget is ultimately the responsibility of the PI
 - Who can be a PI? <https://bit.ly/3cDPwR5>
- Different Sponsors, different rules
 - Always Read the RFP!!
 - Important things to look for in an RFP
- Every College has their own process/preferences
- Budgets are a best estimate – don't underestimate
- Sloppy budgets can hurt, but no budget will win you funding

Proposal Budget

- Budget Spreadsheets – available on Research How 2

<https://bit.ly/3byvC8B>

Sponsoring Agency : National Software Company
 Principal Investigator : Carlotta Valdes
 Period : 09/01/19 thru 08/31/22

Grants / Contracts
3 Year Budget
 Titled : Initech Software Redesign for Y2K (NSC)

						Year 1			Year 2		
						Sal	FB	Total	Sal	FB	Total
A. Salaries											
	<u>Senior Personnel</u>	<u>App't Type</u>	<u>% Effort</u>	<u>PM</u>	<u>Salary</u>						
PI	Carlotta Valdes	ACAD	1.00%	0.07	\$ 108,000	-	\$0	-	-	\$0	-
PI		SUMR	0.00%	0.00	\$ 47,250	-	\$0	-	-	\$0	-
Co	Judy Barton	ACAD	10.00%	0.74	\$ 95,000	9,500	\$2,886	12,386	9,690	\$2,993	12,683
		SUMR	100.00%	3.23	\$ 41,563	41,563	\$12,628	54,191	42,394	\$13,093	55,487
Co	John Ferguson	ACAD	10.00%	0.74	\$ 92,000	9,200	\$2,795	11,995	9,384	\$2,898	12,282
		SUMR	5.00%	0.16	\$ 40,250	2,013	\$612	2,625	2,053	\$634	2,687
Co	Gavin Elster	CAL	3.00%	0.36	\$ 200,000	6,000	\$1,823	7,823	6,120	\$1,890	8,010
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-	\$0	-
<i>Senior Personnel Subtotal :</i>						68,276	20,744	89,020	69,641	21,508	91,149
C. Other Personnel											
	Exempt Staff (Monthly)	Project Manager									
		Midge Wood	20.00%	2.40	\$ 100,000	20,000	7,617	27,617	20,400	7,871	28,271
			0.00%	0.00	\$ -	-	0	0	-	0	0
<i>Total Exempt Staff</i>						20,000	7,617	27,617	20,400	7,871	28,271
	Post Doctoral Support - FLSA Threshold		100.00%	12.01	\$ 47,500	47,500	13,292	60,792	48,450	13,800	62,250
	Graduate Students - Chemistry rate		100.00%	12.01	\$ 23,000	23,000	1,725	24,725	23,460	1,760	25,220
	Undergrad Students 2 for 10 hrs/wk (\$10/hour) for 10 wks		0.00%	0.00	\$ -	2,000	150	2,150	2,040	153	2,193
	Non-Exempt Staff (Bi-Weekly)		0.00%	0.00	\$ -	-	0	0	-	0	0
<i>Sub Totals</i>						160,776	43,528	204,304	163,991	45,092	209,083
<i>Total Salaries and Fringe Benefits :</i>						204,304			209,083		
D. Equipment											
	New Fax Machine					18,000			-		
<i>(Also talk about Participant Support Costs, please)</i>						-			-		
<i>Total Equipment :</i>						18,000			-		
E. Travel											
	Domestic	(list)				4,000			4,080		
	International	(list)				1,000			-		
<i>Total Travel :</i>						5,000			4,080		
G. Supplies and Other Direct Costs											
	Materials & Supplies					5,000			5,100		
	Publication Costs					-			1,000		
	Consultant Services - A. Hitchcock					20			20		
	Hypnotherapy session					1,000			1,020		
	UG Tuition rates (Not Subject to Indirect)					14,468			14,757		
	TPS Reports					1,000			1,020		
	Subcontracts	1) Swingline Stapler company				10,000			15,000		
		2)				-			-		
		3)				-			-		
		4)				-			-		
<i>Total Supplies and Other Direct Costs :</i>						31,488			37,917		
TOTAL DIRECT COSTS:						258,792			251,080		
<i>Facilities and Administrative Costs Calculation:</i>											
<i>Facilities and Administrative Cost Base:</i>						226,324			236,323		
	F&A Cost (on MTDC):		60.50%	60.50%	60.50%	130,876			133,900		
	Sub-Contract <\$25,000 1):		60.50%	60.50%	60.50%	6,050			9,075		

Budget Justification

- Budget Justification Templates – available on Research How 2

<https://bit.ly/2ZbIKzk>

- General
- NSF

Budget Justification University of Cincinnati

Senior Personnel:

No funds are requested the PI of the project, Dr. Carlotta Valdes. Dr. Valdes will lead the research efforts of the project. They will be responsible for the overall design and implementation of all studies. They will also be responsible for compiling data and writing manuscripts for publication as well as progress reports.

Funds are requested for 0.74 (10%) academic months and 3.23 (100%) summer salary for the Co-PI Dr. Judy Barton. This request is based off of an annual salary of \$95,000. Dr. Barton will coordinate all research efforts for the project.

Funds are requested for 0.74 (10%) academic months and 0.16 (5%) summer salary for Co-PI Dr. John Ferguson. This request is based off of an annual salary of \$92,000. They will assist PI with overall design and implementation of all studies.

Funds are requested for 0.36 (3%) calendar months for Co-PI Dr. Gavin Elster. This request is based off of an annual salary of \$200,000. They will be responsible for the overall design and implementation of all animal studies. They will also be responsible for compiling data and writing manuscripts for publication.

University of Cincinnati has personnel who are on academic (9 month) and annual (12 month) appointments. For academic appointments, University of Cincinnati defines a year as the 9-month academic calendar plus up to 3 summer months. The salary calculation for summer months is based on the rate of pay in place in the month of May. For annual appointments, University of Cincinnati defines a year as a period that extends for twelve months, normally beginning on July 1.

Exempt Staff:

Funds are requested for 0.24 (2%) calendar months of kung-fu fan and flare project manager, Midge Wood. This request is based off of an annual salary of \$100,000. Ms. Wood will coordinate administrative efforts of project management.

Post-Doctoral Support:

Funds are requested to support one full time post-doctoral researcher at \$47,500 annually.

Graduate Student:

Funds are requested to support one graduate student. It is anticipated that the graduate student will be involved in the execution of the proposed experiments. The student will be encouraged to plan and execute the most time-intensive experiments and will assist in the research project through conducting reactions and the characterization of compounds. Funds are requested at a base stipend of \$23,000 for the student.

Undergraduate Students:

Fundamentals of Sponsored Administration

Resource	Link
May 3: Introduction to Sponsored Administration	https://bit.ly/2LdhQRI
May 5: Proposal Submission Basics	https://bit.ly/3tlarB3
May 10: Proposal Submission: Opportunities, Budgets, and Justifications	https://bit.ly/3oMlfEV
May 12: Proposal Submission: Grant Review and Award Setup	https://bit.ly/3cyPpsR
May 17: Post Award Management: Fiscal Fundamentals	https://bit.ly/36DNoI2
May 19: Post Award Management: Additional Topics	https://bit.ly/3cE1n4C
May 24: Post Award Management: Audits and Investigations	https://bit.ly/3cBXLQp

Office of Research - Resources

Resource	Link
Office of Research – Coronavirus (COVID-19) and Your Research	https://research.uc.edu/coronavirus-and-your-research
Coronavirus (COVID-19) Updates	https://www.uc.edu/publichealth.html
Office of Research Web Site	research.uc.edu
Office of Research How2	researchhow2.uc.edu
Research Directory Ohio Department of Higher Education – Ohio Innovation Exchange (OIEx)	https://researchdirectory.uc.edu
SPIN – Including COVID-19 Funding Search	research.uc.edu/funding/spin
Limited Submissions Two types – faculty research nominations and research proposals; Selection process dependent on type.	rsrch-webserver.uc.edu/
Office of Research Findings Please sign up to receive this monthly newsletter	https://bit.ly/3d704bf
Early Career Funding Opportunities under Funding on main Office of Research webpage	https://bit.ly/2YqQJqy
Office of Research Annual Report – IMPACT	https://bit.ly/2Ssqo1Cs

Introduction to Federally Funded Clinical Trial Budgets

Kelly Niederhausen

Lisa Schira

Learning Objectives

1. Identify the basic elements of a federal sponsored program budget
2. Distinguish the unique elements of a federal clinical research budget
3. Explain the invoicing process for a federal clinical trial

What's Unique?

- Importance of distinguishing the type of agreement
- Approach to the budgeting process

Types of Agreements

Cost Reimbursable

Sponsor is invoiced based on actual expenses incurred and posted to the grant

- Budget is typically a fixed amount consisting of Direct expenses and indirect (F&A)

Fixed Price

Milestone or Deliverables based

- Each milestone or deliverable has a fixed dollar amount associated with it.

Examples

Cost Reimbursable Language Example

ARTICLE 3. CONDITIONS OF FUNDING

- (a) Payment will be on a cost reimbursement basis. FHI 360 will reimburse only those costs that are identified in the approved Grant budget in Attachment B and are determined to be allowable and allocable under the cost principles followed by FHI 360 and provided in 45 CFR Part 75

Fixed Price Language Example

- 3.4 All Deliverables attained shall be invoiced in accordance with the Subrecipient's budget ("Budget"), attached hereto and incorporated herein as **Exhibit B**. Any proposed increase must be approved in writing by an authorized official of JHU before such commitments may be incurred. In addition,

Milestone	Description of Milestone	Deliverable	Estimated Completion Date	Payment
1	Enrollment Up to a total of 500 participants	Invoice with PTID that will be verified by the CoVPN study sponsor	30 days after Site Initiation	US\$6,539 (50% of per participant cost)

Approach to the budgeting process

Budget Created for Proposal

1. Establish your Budget 'team'
2. Evaluate overall budget limitations – RFA
3. Determine non-salary expenses
4. Determine personnel & effort

Budget Provided by Sponsor

1. Establish your Budget 'team'
2. Evaluate overall budget limitations
3. **Back out F&A**
4. **Determine non-salary expenses**
5. **Determine personnel & effort**

Example – New Trial

Clinical Trial – Disney 001

PI – Mickey Mouse

Coordinator(s): Minnie Mouse, Daisy Duck, Goofy

Projected N = 10

Total Per participant = \$10,000

Start ups and other items - \$50,000

Potential overall Total = \$150,000

Project & Budget Period – 1 year

How do you back into this?

Back out F&A – Determine Directs & Indirects

Total Overall Budget Inclusive of F&A (facilities and administration or Indirects)

Disney 001

F&A Rate = 60%

Direct = \$93,750

Indirect = \$56,250

TOTAL = \$150,000

DIRECTS * F&A RATE = INDIRECTS
DIRECTS + INDIRECTS = TOTAL AWARD

Determine Non-Salary Expense

Total Directs = \$93,750

Determine non-salary expenses

– Expenses per participant = \$1,500* 10 participants
= \$15,000

\$93,750 - \$15,000 = \$78,750 remaining

\$78,750 will be used to cover effort of personnel identified

Determine Personnel Expenses

Determination of personnel & effort:

PI Mickey Mouse – 10%

Coordinator – Minnie – 50%

Coordinator – Daisey – 25%

Coordinator – Goofy – 30%

Budget Template Tool

		Grants / Contracts 1 Year Budget				Titled : <input type="text" value="Disney 001"/>			
Sponsoring Agency :		Walt Disney							
Principal Investigator :		Mickey Mouse							
Period :		01/01/22 thru 12/31/23							
Salaries									
A. AAUP Faculty									
		<u>App't Type</u>	<u>% Effort</u>	<u>PM</u>	<u>Salary</u>	<u>Sal</u>	<u>FB</u>	<u>Total</u>	<u>CUMULATIVE</u>
PI	Mickey Mouse	ACAD	0.00%	0.00	\$ -	-	\$0	-	-
PI		SUMR	0.00%	0.00	\$ -	-	\$0	-	-
Co		ACAD	0.00%	0.00	\$ -	-	\$0	-	-
		SUMR	0.00%	0.00	\$ -	-	\$0	-	-
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
<i>AAUP Faculty Subtotal :</i>						-	0	0	-
B Dual Compensation Faculty									
Co	Mickey Mouse	CAL	10.00%	1.20	\$100,000	10,000	\$3,625	13,625	13,625
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
Co		CAL	0.00%	0.00	\$ -	-	\$0	-	-
<i>Dual Comp Faculty Subtotal :</i>						10,000	3,625	13,625	13,625
C. Other Personnel									
Exempt Staff (Monthly)		<u>Name</u>	<u>% Effort</u>	<u>PM</u>	<u>Salary</u>				
		Minnie Mouse	50.00%	6.00	\$ 55,000	27,500	8,690	36,190	36,190
		Daisy Duck	25.00%	3.00	\$ 40,000	10,000	3,160	13,160	13,160
		Goofy	30.00%	3.60	\$ 40,000	12,000	3,792	15,792	15,792
			0.00%	0.00	\$ -	-	0	0	-
<i>Total Exempt Staff</i>						49,500	15,642	65,142	65,142
		Post Doctoral Support	0.00%	0.00	\$ -	-	0	0	-
		Graduate Students	0.00%	0.00	\$ -	-	0	0	-
		Undergrad Students	0.00%	0.00	\$ -	-	0	0	-
		Part-time Faculty/Staff	0.00%	0.00	\$ -	-	0	0	-
		Non-Exempt Staff (Bi-Weekly)	0.00%	0.00	\$ -	-	0	0	-
<i>Sub Totals</i>						59,500	19,267	0	-
Total Salaries and Fringe Benefits :						78,767		78,767	

Budget Template Tool

G. Supplies and Other Direct Costs

Materials & Supplies		15,000	15,000
LAM		-	-
Consultant Services		-	-
Computer Services		-	-
UC Tuition rates (Not Subject to Indirect)		-	-
Long Distance		-	-
Other (Analytical Services/Instrument Use)		-	-
Subcontracts	1)	-	-
	2)	-	-
	3)	-	-
	4)	-	-
<i>Total Supplies and Other Direct Costs :</i>		<u>15,000</u>	<u>15,000</u>
	TOTAL DIRECT COSTS:	93,767	93,767
	<i>Facilities and Administrative Cost Base:</i>	<i>93,767</i>	<i>93,767</i>
<u>Facilities and Administrative Costs Calculation:</u>			
F&A Cost (on MTDC):	60.00%	56,260	56,260
Sub-Contract <\$25,000 1):	60.00%	0	0
Sub-Contract <\$25,000 2):	60.00%	0	0
Sub-Contract <\$25,000 3):	60.00%	0	0
Sub-Contract <\$25,000 4):	60.00%	0	0
<i>Total F&A Cost :</i>		<u>56,260</u>	<u>56,260</u>
Total Cost		<u>150,027</u>	<u>150,027</u>

Considerations in Budgeting

Large shortfall in budget

- What can be reduced and makes sense to reduce?
- Is it feasible to accept this study?
- Are the estimates overstated?
- Would it be appropriate to request additional funds from the sponsor?

Large excess in the budget

- Carefully consider if enough effort is being allocated?
- Are we underestimating expenses? Something missing?
- Will there be a large surplus at the end of the study?

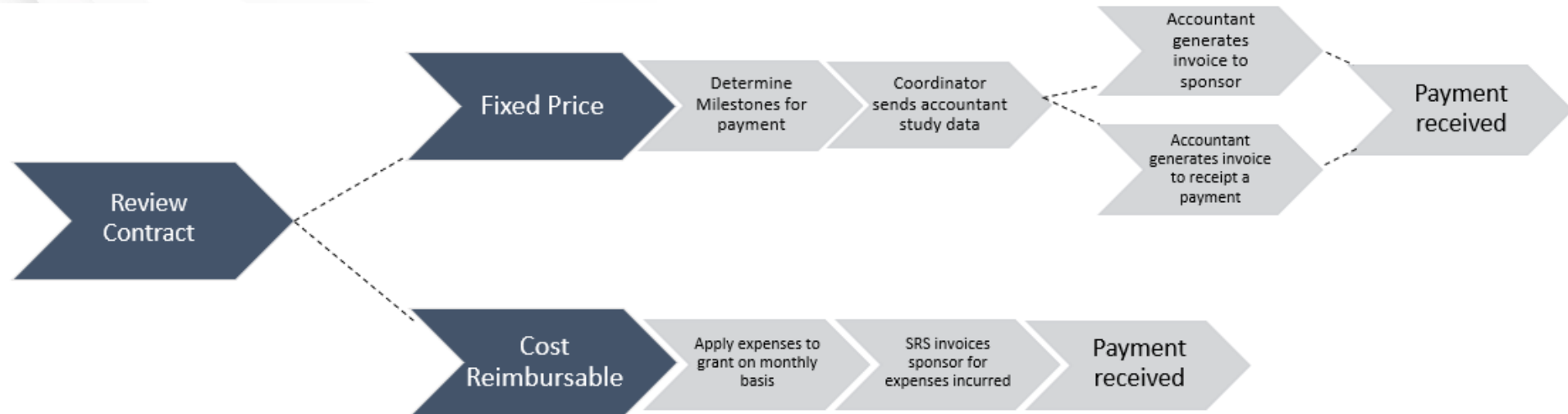
PLAN FOR THE BUDGET TO BE FULLY UTILIZED

Invoicing Contacts for Clinical Trials

Communication is Key

- COM Accountant
- Business Administrator or Manager
- SRS (Sponsored Research Services) –
Accountant & Grants Administrator

Invoicing Process for Clinical Trials



Invoicing Process for Clinical Trials

Study Info

- Enrolled 3 patients
- Enrollment visit and visit 1 completed
- Start ups

Milestone Payments:

Milestone # 1 Enrollment -
\$1,000

Milestone # 2 Visit 1 - \$3,000

Milestone # 3 Visit 5 - \$3,000

Milestone # 4 Final Visit - \$3,000

Invoicing preparation steps

1. Provide enrollment data to Accountant or Business office
2. Business representative determines which milestones can be invoiced based on the data
3. Spreadsheet tracking the milestones

Example – Tracking Milestones & Invoices

	A	B	C	D	E	F	G	H	I	J
1		Amount	Date invoiced							
2	Start Ups	\$ 10,000	4/2/2021							
3										
4	Patient ID	Milestone # 1 Enrollment	Date invoiced	Milestone # 2 Visit 1	Date invoiced	Milestone # 3 Visit 5	Date invoiced	Milestone # 4 Final Visit	Date invoiced	TOTAL
5	001	\$ 1,000	4/2/2021	\$ 3,000.00	4/2/2021					\$ 4,000
6	002	\$ 1,000	4/2/2021	\$ 3,000.00	4/2/2021					\$ 4,000
7	003	\$ 1,000	4/2/2021	\$ 3,000.00	4/2/2021					\$ 4,000
8										\$ -
9										\$ -
0										\$ -
1										\$ -
2										\$ -
3										\$ -
4										\$ 12,000

Invoice #	Date of Invoice	Amount	Date of posted payment
123456	4/2/2021	\$ 22,000	
TOTAL INCOME		\$ 22,000	



WRAP UP!

1. Distinguish Agreement Type
2. Account for F&A and back into any fixed amounts
3. Communication is key in invoicing



QUESTIONS???