Clinical Trial Account Close Out

Clinical Research Finance and Administration

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Clinical Trials

Clinical Trial Agreements:

- Generally do not have end dates
- Allow UTHealth to retain remaining funds at the end of a study

UTHealth has historically extended the end date to allow the investigator to spend remaining funds

Clinical Trials

- Studies Closed After August 1, 2016
 - Initiated by Clinical Research Finance and Administration
 - Projects with Fund # 57001
 - Close process is triggered by the study protocol closed in the IRB system
 - CRF conducts full review of study and report to department with balance transfer recommendations
 - Department reviews and approves or modifies and approves closeout and balance transfer

Contract Residual Accounts

- Indirect Costs are deducted from the remaining total balance and transferred to the indirect cost fund for further distribution
- ❖ Direct Cost balances from clinical trials or other fixed fee awards (Fund #57001) must be transferred to a residual balance account after termination
- Contract Residual Accounts are specific to each individual PI
- Department Residual Accounts are projects accounts specific to each individual department under the Chair's name

Requested Account Closeout

- 1. All the work is complete
- 2. All funds have been received
- 3. All obligations have been met
- 4. All Encumbrances are cleared
 - Encumbrances/Pre-encumbrances: Obligated funds that have not been expensed

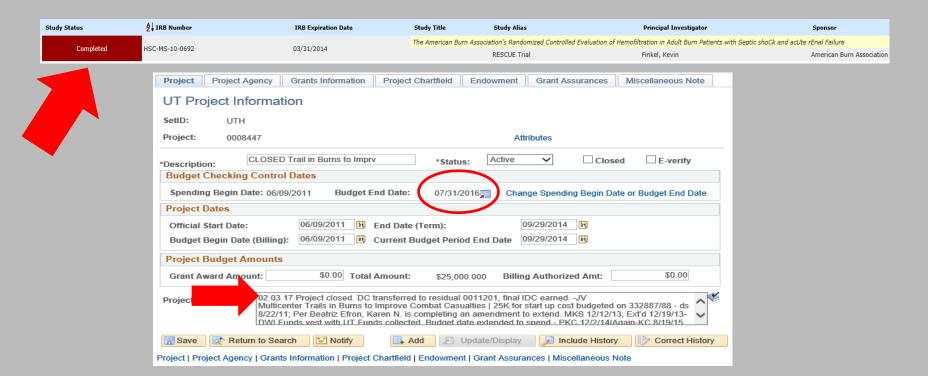
Automatic Account Closeout

- 1. All the work is complete
- 2. One year after study is closed with the IRB
- 3. All funds have been received
- 4. All obligations have been met
- 5. All encumbrances are cleared
 - Encumbrances/Pre-encumbrances: Obligated funds that have not been expensed

Account Closeout Process

- 1. Study team submits IRB closure report in Iris
- CRFA team identifies all studies closed at the end of month
- 3. CRFA team extends spend date on fms account
- 4. CRFA team performs account analysis
- 5. Department signs off on direct cost split, or revises
- 6. CRFA team performs journal entries to move funds

IRB Status and FMS Spend Date



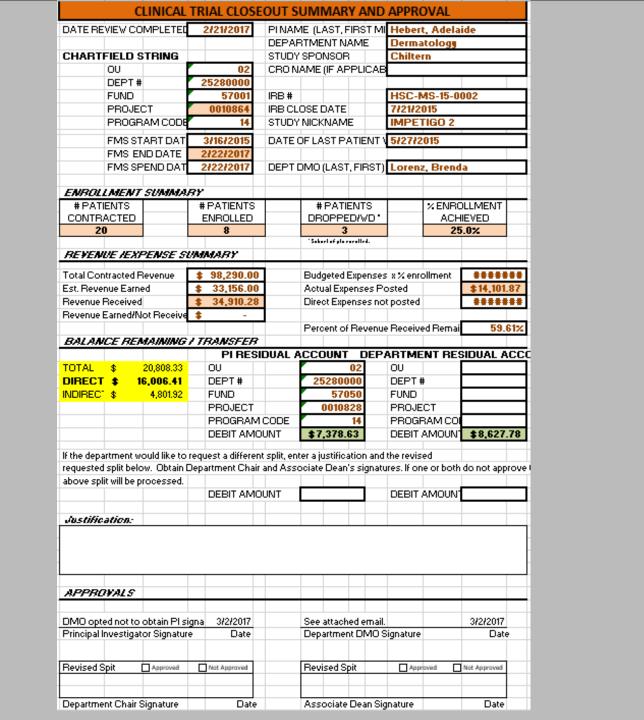
Level of Review

CRF's full review includes:

- Enrollment/percent completed stats
- Revenue earned/received
- Document revenue earned not received, not invoiced
- Calculate/analyze expenses incurred/not posted (salaries, patient care, patient stipends, IRB fees only)
- Recommended balance transfer split

Clinical Trial Closeout Summary and Approval Form

- CRF analyst provides a full financial review of the research project
- DMO has option to recoup department funds expensed but not charged to the project
- Once approved- Analyst will close the project to a residual account



REYENUE DETAIL					
	Budgeted	Est. Earned	Received	ned, Not	t Received
Per Patient & StartUp					-
Amount Per Completed Pt.	\$ 3,972.00	3,972.00			
Number Pts. Completed	20.00	5.00			
Total Per Completed Patient	\$ 79,440.00	######	\$ 19,860.00	\$	
Start Up Fees	\$ 6,500.00	\$6,500.00	\$ 6,500.00	\$	
Screen Fail and Early Term	\$ 400.00	\$ 2,154.28	\$ 2,154.28		
Total Automatic	\$ 85,940.00	######	\$ 28,514.28	\$	
Paid upon Invoice/one t	ime				
IRB - Initial	\$ 2,600.00	2,600.00	2,600.00		
SIV Staff Time	\$ 1,300.00	1,300.00	1,300.00		
	1 1,211.13	,,,,,,,,	4		
Document Retention	\$ 1,300.00	1,300.00	1,300.00		
Training	\$ 650.00	650.00	650.00		
Advertising	\$ 6,500.00	546.00	546.00		
			-		
	\$ 12,350.00	\$6,396.00	\$ 6,396.00	\$	
Paid upn invoice/per pat					
IRB - Amend/Continue					
Inb - Amendrondinde			- :		
			-		•
			-		-
			-		
	-		\$ -		-
TOTALC	\$ -	\$ -	-	\$	<u> </u>
TOTALS	\$ 98,290.00	######	\$ 34,910.28	\$	
Revenue Notes					
nevenue wores					
Based on review of revenue, w	ve were paid for re	evenue earned per	patient.		
	we were paid for re	evenue earned per	patient.		
	we were paid for re	evenue earned per	patient.		
Based on review of revenue, w				Not Ex	pensed
Based on review of revenue, w	we were paid for re	Budgeted \$ 3,471.25	Expensed	Not Ex	pensed 3,471.2
Based on review of revenue, w	% Enrolled 25.0%	Budgeted	Expensed		
EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe Patient Care	% Enrolled 25.0%	Budgeted \$ 3,471.25 \$ 2,260.50	Expensed	\$	3,471.2 2,260.5
EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe	% Enrolled 25.0%	Budgeted \$ 3,471.25 \$ 2,260.50	Expensed \$ -	\$	3,471.2 2,260.5 (995.0
EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe Patient Care Patient Stipend \$50 x 4 visits	% Enrolled 25.0%	Budgeted \$ 3,471.25 \$ 2,260.50 \$ - 3 \w \$ 1,900.00	Expensed \$ - \$ - \$ 995.00	\$ \$ \$ \$	3,471.2 2,260.5 (995.0
EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe Patient Care Patient Stipend \$50 x 4 visits Other M&O	% Enrolled 25.0%	Budgeted \$ 3,471.25 \$ 2,260.50 \$ 3 \& \$ 1,900.00	Expensed \$ - \$ 995.00	\$ \$ \$ \$ \$	3,471.2 2,260.5 (995.0 1,900.0
EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe Patient Care Patient Stipend \$50 x 4 visits Other M&O TOTAL DIRECT	% Enrolled 25.0% e 	Budgeted \$ 3,471.25 \$ 2,260.50 \$ 3 \\ \$ 1,900.00 \$ - \$ 7,631.75	Expensed \$ - \$ 995.00 \$ -	\$ \$ \$ \$ \$	3,471.2 2,260.5 (995.0 1,900.0 6,636.7
Based on review of revenue, v EXPENSE DETAIL PI Salary/Fringe Study Personnel Salary/Fringe Patient Care Patient Stipend \$50 x 4 visits Other M&O	% Enrolled 25.0% e 	Budgeted \$ 3,471.25 \$ 2,260.50 \$ 3 \& \$ 1,900.00	Expensed \$ - \$ 995.00	\$ \$ \$ \$ \$	3,471.2 2,260.5 (995.0 1,900.0

Total expenses = \$14,101.87 But the majority of the expenses are not related to the study and occured after the study ended with the exception of patient care costs. No patient care costs were budgeted but they did occur when the study was active.