

Clinical Trial Account Close Out

Clinical Research Finance and Administration

*Presentation created by: John Valenta
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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
2. 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

Study Status	IRB Number	IRB Expiration Date	Study Title	Study Alias	Principal Investigator	Sponsor
Completed	HSC-MS-10-0692	03/31/2014	The American Burn Association's Randomized Controlled Evaluation of Hemofiltration in Adult Burn Patients with Septic shock and acute renal Failure	RESCUE Trial	Finkel, Kevin	American Burn Association



UT Project Information

SetID: UTH
Project: 0008447

Budget Checking Control Dates
Spending Begin Date: 06/09/2011 Budget End Date: 07/31/2016 [Change Spending Begin Date or Budget End Date](#)

Project Dates
Official Start Date: 06/09/2011 End Date (Term): 09/29/2014
Budget Begin Date (Billing): 06/09/2011 Current Budget Period End Date: 09/29/2014

Project Budget Amounts
Grant Award Amount: \$0.00 Total Amount: \$25,000.00 Billing Authorized Amt: \$0.00

Project Description: 02.03.17 Project closed. DC transferred to residual 0011201. final IDC earned. -JV Multicenter Trails in Burns to Improve Combat Casualties | 25K for start up cost budgeted on 332887/88 - ds 8/22/11; Per Beatriz Efron, Karen N. is completing an amendment to extend. MKS 12/12/13; Ext'd 12/19/13-DWL Funds vest with IIT Funds collected. Budget date extended to spend - PKC 12/2/14 Again-KC 8/19/15

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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

CLINICAL TRIAL CLOSEOUT SUMMARY AND APPROVAL

DATE REVIEW COMPLETED	2/21/2017	PI NAME (LAST, FIRST MI)	Hebert, Adelaide
		DEPARTMENT NAME	Dermatology
CHARTFIELD STRING		STUDY SPONSOR	Chiltern
OU	02	CRO NAME (IF APPLICABLE)	
DEPT #	25280000		
FUND	57001	IRB #	HSC-MS-15-0002
PROJECT	0010864	IRB CLOSE DATE	7/21/2015
PROGRAM CODE	14	STUDY NICKNAME	IMPETIGO 2
FMS START DATE	3/16/2015	DATE OF LAST PATIENT VISIT	5/27/2015
FMS END DATE	2/22/2017		
FMS SPEND DATE	2/22/2017	DEPT DMO (LAST, FIRST)	Lorenz, Brenda

ENROLLMENT SUMMARY

# PATIENTS CONTRACTED	# PATIENTS ENROLLED	# PATIENTS DROPPED/WD*	% ENROLLMENT ACHIEVED
20	8	3	25.0%

*Subset of pts recalled.

REVENUE / EXPENSE SUMMARY

Total Contracted Revenue	\$ 98,290.00	Budgeted Expenses % enrollment	*****
Est. Revenue Earned	\$ 33,156.00	Actual Expenses Posted	\$14,101.87
Revenue Received	\$ 34,910.28	Direct Expenses not posted	*****
Revenue Earned/Not Received	\$ -	Percent of Revenue Received Remaining	59.61%

BALANCE REMAINING / TRANSFER

	PI RESIDUAL ACCOUNT	DEPARTMENT RESIDUAL ACCOUNT
TOTAL \$ 20,808.33	OU 02	OU
DIRECT \$ 16,006.41	DEPT # 25280000	DEPT #
INDIRECT \$ 4,801.92	FUND 57050	FUND
	PROJECT 0010828	PROJECT
	PROGRAM CODE 14	PROGRAM CODE
	DEBIT AMOUNT \$7,378.63	DEBIT AMOUNT \$8,627.78

If the department would like to request a different split, enter a justification and the revised requested split below. Obtain Department Chair and Associate Dean's signatures. If one or both do not approve the above split will be processed.

DEBIT AMOUNT		DEBIT AMOUNT	
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Justification:

APPROVALS

DMD opted not to obtain PI signature	3/2/2017	See attached email.	3/2/2017
Principal Investigator Signature	Date	Department DMD Signature	Date
Revised Split	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved	Revised Split	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
Department Chair Signature	Date	Associate Dean Signature	Date

REVENUE DETAIL

	Budgeted	Est. Earned	Received	ded, Not 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 time				
IRB - Initial	\$ 2,600.00	2,600.00	2,600.00	-
SIV Staff Time	\$ 1,300.00	1,300.00	1,300.00	-
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 upon invoice/per patient				
IRB - Amend/Continue			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
	\$ -	\$ -	\$ -	\$ -
TOTALS	\$ 98,290.00	#####	\$ 34,910.28	\$ -

Revenue Notes

Based on review of revenue, we were paid for revenue earned per patient.

EXPENSE DETAIL

	% Enrolled	Budgeted	Expensed	Not Expensed
PI Salary/Fringe	25.0%	\$ 3,471.25	\$ -	\$ 3,471.25
Study Personnel Salary/Fringe		\$2,260.50	\$ -	\$ 2,260.50
Patient Care		\$ -	\$ 995.00	\$ (995.00)
Patient Stipend \$50 x 4 visits x 8 pts + \$300 for 3 w		\$ 1,900.00	\$ -	\$ 1,900.00
				\$ -
Other M&O		\$ -		\$ -
TOTAL DIRECT		\$ 7,631.75	\$ 995.00	\$ 6,636.75
TOTAL INDIRECT @ 30%		2,289.53	\$ 298.50	\$ 1,991.03
TOTAL EXPENSES		\$ 9,921.28	\$ 1,293.50	\$ 8,627.78

Total expenses = \$14,101.87 But the majority of the expenses are not related to the study and occurred 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.