

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

**ENROLLMENT SUMMARY**

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

\*Subset of pts recalled.

**REVENUE / EXPENSE SUMMARY**

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

**BALANCE REMAINING / TRANSFER**

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

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**

DMO opted not to obtain PI signature	3/2/2017	See attached email.	3/2/2017
Principal Investigator Signature	Date	Department DMO 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
<b>Per Patient &amp; StartUp</b>				
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	\$ -
<b>Paid upon Invoice/one time</b>				
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	\$ -
<b>Paid upon invoice/per patient</b>				
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.