Clinical Trials Post Award

December 14, 2021

Sponsored Clinical Trial:

A research study that prospectively assigns human participants or groups of human participants to one or more health-related interventions to evaluate the effects on health outcomes, the costs for which are paid to LSUHSC-NO by a non-LSUHSC-NO entity such as, although not limited to, a pharmaceutical company.

DEFINITIONS

<u>Clinical Trial Agreement (CTA)</u>: an agreement with the sponsor as to an amount and how reimbursement will be made per the clinical trial agreement.

<u>IRB Fees</u>: one-time and/or recurring expenses charged to most sponsored clinical trials by LSUHSC-NO's Institutional Review Board, which provides review and approval of all research projects involving the use of human subjects, with the purpose of protecting the rights and welfare of individuals participating in those projects.

<u>ClinCards</u>: reloadable debit cards that are used as a method of paying human clinical trial subjects for their trial participation or to reimburse them for participation-related expenses.

Management of Clinical Trial

Departments are responsible for ensuring that clinical trial expenditures and revenues are applied appropriately to the correct PeopleSoft Project.

BI Publisher reports are available to review project totals compared with budget totals

ZZGLX021

BU Summary Report All Groups

Sponsored Projects Administration (SPA) will send departments a list of clinical trials on a (monthly, quarterly, etc., basis). Departments should inform SPA if a trial has ended or if an IRB has been extended.

It is important for us to know if a clinical trial is active or concluded.

A bad end date can result in budget errors and/or processing issues for Prospective / Retrospective Per3 transactions.

Example of BI Publisher Report

			LS	UNO Summar	un Date & Time:	7/30/2021	17:45:09 PM			
								As of Period: 12	Year: 2021	
Acct	Description	A Prior YR Budg Bal	B Current YR Budg Adj	C Current YR Budg Bal	D Current Period Actual	E Fiscal YTD Actuals	F Project to Date Actuals	G Open Commitments	H Actuals plus Commitments	l Surplus/(Deficit) Budget Balance Available
Proj: 14970 CFDA 93.107	00 - M_S-Multidisciplinary 07 20 20 XOTXKH28X080C3	CHANNEXXXX	Fund:113 F&A%: 8	Progra PI:	m:00001	Class:20200 Ref#: HRSA 2U77HP03041-21-0		MODEL STATE SUP	PORTED AHEC	
420110	Federal Sponsored Programs	(95,455.00)	0.00	(95,455.00)	(17,438.36)	(67,374.92)	(67,374.92	0.00	(67,374.92	(28,080.08)
	Bud Level 42	(95,455.00)	0.00	(95,455.00)	(17,438.36)	(67,374.92)	(67,374.92	0.00	(67,374.92)	(28,080.08)
Revenue		(95,455.00)	0.00	(95,455.00)	(17,438.36)	(67,374.92)	(67,374.92)	0.00	(67,374.92)	(28,080.08)
toronuo	Total Revenues	(95,455.00)	0.00	(95,455.00)	(17,438.36)	(67,374.92)	(67,374.92)		(67,374.92)	
530000	Operating Services	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.0	0.00
	Bud Level 53	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
540000	Supplies	12,892.00	0.00	12,892.00	0.00	0.00	0.0	0.00	0.0	0 12,892.00
540103	Taggable-Computer Hardware	0.00	0.00	0.00	0.00	2,203.00	2,203.0	0.00	2,203.0	0 (2,203.00)
546700	Office Supplies	0.00	0.00	0.00	0.00	146.15	146.1	5 0.00	146.1	5 (146.15)
547200	Other Supplies	0.00	0.00	0.00	0.00	1,044.21	1,044.2	1 0.00	1,044.2	1 (1,044.21)
	Bud Level 54	12,892.00	0.00	12,892.00	0.00	3,393.36	3,393.36	0.00	3,393.36	9,498.64
550000	Professional Services	75,492.00	0.00	75,492.00	0.00	0.00	0.0	0.00	0.0	0 75,492.00
557000	Subcontract & Consor-Spon Proj	0.00	0.00	0.00	6,607.39	70,317.49	70,317.4	9 0.00	70,317.4	9 (70,317.49)
	Bud Level 55	75,492.00	0.00	75,492.00	6,607.39	70,317.49	70,317.49	0.00	70,317.49	5,174.51
Direct Expe	enses	88,384.00	0.00	88,384.00	6,607.39	73,710.85	73,710.85	0.00	73,710.85	14,673.15
590000	Facility & Admin Costs Recover	7,071.00	0.00	7,071.00	0.00	0.00	0.0	0.00	0.0	0 7,071.00
592000	F & A Costs Recov-Departments	0.00	0.00	0.00	0.00	70.58	70.5	8 0.00	70.5	8 (70.58)
595000	F & A Costs Recov-Admin	0.00	0.00	0.00	0.00	144.21	144.2		144.2	
597000	F & A Costs Recov-Use Allow	0.00	0.00	0.00	0.00	56.67	56.6	7 0.00	56.6	7 (56.67)
	Bud Level 59	7,071.00	0.00	7,071.00	0.00	271.46	271.40	0.00	271.46	6,799.54
Indirect Ex	penses	7,071.00	0.00	7,071.00	0.00	271.46	271.46	0.00	271.46	6,799.54
	Total Expenses	95,455.00	0.00	95,455.00	6,607.39	73,982.31	73,982.31	0.00	73,982.31	21,472.69
	Total for Project: 149760129B	0.00	0.00	0.00	(10,830.97)	6,607.39	6,607.39	0.00	6,607.39	21,472.69

Project Set Up

Upon receipt of a fully executed clinical trial agreement, departments are required to request a new project/chart string from SPA. The form is located on the SPA website. https://www.lsuhsc.edu/administration/accounting/sponsored_projects_links_pathways.aspx

Documents to submit with the request for new project/chart string include the following:

- Clinical Trial Agreement and/or Subaward agreement
- Copy of routing sheet / approval documentation from the Kuali system
- Proof of regulatory approval (IRB/IBC) needed to conduct the clinical trial
- Medicare Cost Analysis
- 3 Keywords applicable to the clinical trial
- Cost sharing documentation if applicable

Note:

Clinical Trials must have an approved IRB in order to start the research. Clinical Trials must have a Medicare Coverage Analyses completed.

Clinical Trial Agreement End Date Extension

In order for SPA to extend the end date of a clinical trial the following information is needed:

- Copy of the Active IRB
- Clinical Trial Agreement with an updated end date, should the agreement have a stated end date

Send Request to extend the end date along with the documentation stated above to Nosponproj@lsuhsc.edu

IRB Fee Invoicing

Departments will be responsible to invoice the sponsor(s) for the IRB fee.

The invoice should to be routed through SPA for the Accounts Receivable processing.

Please send these invoices to: <u>ClinicalTrials@lsuhsc.edu</u>

IRB fees should match the amount charged to the project and not necessarily the CTA Exhibit.

If there is a difference between the IRB fee(s) listed on the CTA schedule and the IRB fee(s) posted to the project, please contact the Office of Research Services.

If it is determined the IRB fees charged on the project are appropriate and are accurately reflected in the ledger then we will need documentation of what IRB fee was allowed and a Justification as to why the difference occurred.

CURRENT LSUHSC-NO HRPP FEE SCHEDULE#

IRB of Record	Review Type	Fee
LSUHSC-NO IRB	Initial-Full Board	\$2,500 per study
	Initial-Expedited	\$1,500 per study
	Initial-Exempt	\$1,000 per study
	Continuing-Full Board*	\$1,000/\$1,500* each
	Continuing-Expedited*	\$500/\$750* each
	Modification-Full Board	\$500 each
	Modification-Expedited (personnel changes excluded)	\$250 each

Processing of Invoicing on Clinical Trials

Departments will need to submit copies of all clinical trial invoices along with back up documentation to <u>ClinicalTrials@lsuhsc.edu</u>

SPA will enter the receivable into the Accounts Receivable system.

Billing and Accounts Receivable will apply payments to the open receivable.

Clinical Trial Invoice Documentation

Invoices should indicate the PeopleSoft Project Number, the Study Title, and the Sponsor Name.

Invoices should be clear as to what amount is being charged for each study participant.

Invoices should be reconciled to the Clinical Trial Exhibit of agreed upon charges. Please note, any differences between what was billed and the CTA agreement need justification.

A few examples are listed below:

Week 8 on the CTA states we should bill for an MRI but the MRI was not preformed therefore we could not invoice for it.

A participant could not see the Principal Investigator on week 14 but saw a Nurse instead and therefore the visit was not an allowable charge.

Backup documentation should be included with the invoice when submitted to SPA along with any justification for deviation(s) from the CTA.

Invoices should indicate the approval/certification of the Principal Investigator, Business Manager, and Clinical Trials Coordinator or Nurse.

Example of CTA Exhibit

TABLE 1

-

Protocol: WO29522 Study Center: LSU Health Sciences Center Investigator: Michelle Loch, M.D.

Contract # 197084

STUDY PHASE III STUDY CYCLE	Screening		Cycle 1		T	Cycle 2		1	Cycle 3		T
STODY CICLE			Cycle I			Cycle z	-		Cycle 3	1	+
DAY	Days -28 to -1	1	8 (+/-3)	15 (+/-3)	1	8 (+/-3)	15 (+/-3)	. 1	8 (+/-3)	15 (+/-3)	1
PROCEDURE COSTS							Provide Sulfa				discourse and
nformed consent	\$150	No. of Lot of Lot	Constanting of the	Spice Mar	molassi ser	Mr. Aller	Allow States and a la	The second second	Marriella Marriella	The Street In Lords	Contraction and
Inclusion/Exclusion	\$53		a service states	Cale M. Stable			14-1-128-34	The state of the state	and the second second	State - State	32 × 2005
HIV, HBV, HCV serology	\$100		The second second	Salla Caret	Presidentes	State and and	a har a star	1 million and the second	all and a second	and the second second	12200
Concomitant Meds	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27
Tumor Response Assessments (RECIST)	\$150	\$150	And the Martin		I CONTRACTOR		and the state	\$150	Contraction and the second	Sec. He	- Participant
Scans	SOC/INV	\$2,600	State and a	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	CONSTRUCTION OF	Carl and the set	CALLS IN THE	\$2,600	No. Contraction in	1 Carlos Contra	Television and
lead CT or MRI	SOC/INV	and the second of			1222	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	The states	ALC: NO DE LA COMPANY	State States	10 miles	Contraction of the local division of the loc
Patient-Reported Outcomes (EORTC QLQ-C30, QLQ-BR23, and EQ-5D-5L)		\$27		1. Starting	\$27			\$27			\$27
Complete physical examination (includes demographics; medical, surgical and cancer histories; baseline conditions; vitals; weight; height)	Routine										
Limited physical examination (includes weight; height)	and the second second	Routine			Routine	Contraction of the	A State of the state	Routine	2.1.32	1	Routine
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2-Lead Electrocardiogram, tracing only	x	0.0	010		0.0	010	010	e lu	010	1 510	\$10
Hematology	\$11	SOC	\$11	\$11	SOC	\$11	\$11	SOC	\$11	\$11	SOC
Serum Chemistry	\$12	SOC	\$12	\$12	SOC	\$12	\$12	SOC	\$12	\$12	SOC
Magnesium and Phosphorus	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10
Coagulation Panel (aPTT, INR)	\$15	COMPANY AND	Constant and a	States and states	And States of the	N- READER	A State of the state of the	Company Courses	Contraction of the	415	010
Central Labs (EBV serology; C-reactive protein testing; auto-antibody testing; serum sample for ATA assessment; serum sample for Atezolizumab PK sampling; plasma samples for nab-pacitaxel; TBNK blood samplo; blood samples for PD biomarkers): Blood Draw, Sample Collection of Specimens Includes Prep and Processing)	\$180	\$180			\$180			\$180			\$180
Jrinalysis	\$11	Set and	1	and the second second	1000 1000	And all and a list	STATE!	X		1	1
Pregnancy Test	INV	INV	Carl Contraction	PRIME TO ANY	INV	ALT NOT M	and the state	INV	State 20	A REAL PROPERTY OF	INV
SH, free T3, free T4	\$43	10400	all she was at	2.3	and the second second	Constant of the	A STREET OF	1,555,524			A COLOR
Optional whole blood sample for RCR DNA	STON BUSICESS	INV ***	- Shares	Section and	Care and the second	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	State -	Maria Cara an	a salara		TO SECT
Adverse Events		\$159	\$159	\$159	\$159	\$159	\$159	\$159	\$159	\$159	\$159
Drug Dispensing	なったちのないのこのでな	\$60	\$30	\$60	\$60		\$60	\$60	\$30	\$60	\$60
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Survival and anti-cancer therapy follow-up	San States	TRACT (DEP)(TRA	the second second		CONTRACTOR OF STREET	and the second second		Reserved and	and the second second	Contraction of the local	March Contractor

Minvoice Number NG22-0123 -Minvoice Date 12/02/2021 \$558.51 ____ **INVOICE EXAMPLE** Invoice Amount The invoice number will be generated in the AR system by SPA SPA will also add the invoice date to invoice INFOICE BILL TO: Genetech, Inc. REF Attn: Stacy Maryannis, Senior Study Manager Protocol # WO29522 45-4216-9 Mail Stop 454B IRB# 9390 LSUHSC Proj # 149740318A 1 DNA Way South San Francisco, CA 94080 Email: wo29522_ops-d@gene.com FOR SERVICES RENDERED UNDER PROJECT TITLED: A Phase III, Malikonier, Randomica, Placeho-Controlled Study of ATEZOLIZUMAB (Anti-PD-L1 Antibody) in Combination with NAB-PACLITAXEL for Patients with Previously Untrated Medicatist Triph-Pacient Breast Cancer LSUHSC PI Michelle Loch, MD DESCRITION OF SERVICES: Subject ID Price per CTA Exhibit Quantity Description Amount 21-0000 Cycle 2; Day 8 (+/- 3) 27.00 Concomitant Meds 27.00 12.51 Vital Signs 12.51 Hematology 11.00 12.00 11.00 Serum Chemistry 12.00 Magnesium and Phosphorus Adverse Events 10.00 10.00 159.00 159.00 Investigator Study Coordin 175.00 175.00 53.00 0.00 Data Management 30.00 30.00 Overhead Costs (25%) 122.00 1 122.00 Total per CTA exhibit 611.51 Note: Invoice amount doesn't match the CTA exhibit amount. A justification form will need to be completed Total Invoice [Line is formula driven] 558.51 "By signing this report, I contrify to the best of my knowledge and belief that the report is true, complete, and accurate and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the agreement." Susie Green, Clinical Trials Nurse Coordinator Date "By signing this report, I have reviewed this invoice and to the best of my knowledge certify its accuracy based on the schedule of assessments/badget as stipulated in the agreement." Date Michelle Loch MD, Principal Investigator For questions regarding this invoice, please contact: Barbara Landrum, Business Manager of Cancer Center Date Sarah Smith Name: Phone: Fax: 504.568.4857 504.568.1234 smith@lauhsc.odu Email MAKE CHECKS PAYABLE AND REMIT TO: Louisiana State University Health Sciences Center - New Orleans Sponsored Projects Ref. [W029522 / Loch / 149740318A]

Example of Backup Document Needed

Subject ID	Proje	ct Number									
TABLE 1											
	WO29522	man Candor									
	LSU Health Scien Michelio Loch, M.										
Contract #		W .									
	127000										
STUDY PHASE III		1									
STUDY CYCLE	Screening		Cycle 1			Cycle 2			Cycle 3		1
			-	15							
DAY	Days -28 to -1	1	(+/-3)	(+/-3)	1	E [+/-3]	15 (+/-3)	. 1	\$ (+/-3)	15 (+/-3)	1
PROCEDURE COSTS	8 Jac -	and the second second								12	
informed consent	\$150	The second second	A STATE CORRECTOR	A REAL AND A	and the second second	A STATE OF	Nogi Charge	The second is the	A BARRELE PARTY	Charles and the	ALL STREET
Inclusion/Exclusion	\$63	12.00	0.000002383	Change and	COLUMN OF	Carlot Strategy of	1	The state of the state	A CARLES		All Back of the
HIV. HBV, HCV serology	\$100	The second second	and the state	a la tara		The second second	A Stand	and the second second	Selection and the		12000000000000
Concomitant Meds	\$27	\$27	\$27	\$27	\$27	\$27	\$27	827	\$27	\$27	\$27
Tumor Response Assessments (RECIST)	\$1.50	\$150		and the second	1	1 1 2	acres	\$150	Vannen -	1	- Print Contin
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ECOG Performance Status	\$13	\$13		10000	\$13	ALL TANKER	1405-1 (mar-	\$13		-	\$13
Vital Signs	and the second	613	\$13	\$13	\$13	\$13	\$13	\$13	\$13	313	\$13
12-Lead Electrocardiogram, tracing only	x	0.0	1			1 0.0		410		919	0.0
Hematology	\$11	SCC	\$11	\$11	\$00	\$11	511	SOC	\$11	\$11	800
Serum Chamistry	\$12	SOC	812	312	SDC	512	\$12	SOC	\$12	\$12	SOD
Magnesium and Phosphorus	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10
Coagulation Panel (aPTT, INR)	\$15	CONTRACTOR OF	CONTRACTOR OF		man Philippine	And Address of the	a service beaution	Contraction of the local division of the			
Central Labs (EBV serology; C-reactive protein testing; auto-antibody tosting;			Sample and the	A PATER STRATE		1.7.2-14-58.7.1.7.4	and the second second			AX 1 35 343.14	
serum sample for ATA assessment; serum sample for Alegolizumat; PK sampling; plasma samples for not-osciltaxel; TBNK bloed eamplo; blood	\$180	\$180			\$180	11-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	1.5	\$160	TT POTALS		\$150
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Adverse Events	And the same literation	\$159	\$159	\$159	\$159	\$159	\$159	\$159	\$169	\$159	\$159
Drug Dispensing	Charles 44-19-19-19	\$60	\$30	\$60	\$50		\$50	360	\$30	560	\$60
Atezolizumab/placebo infusion	Martin Par	Routine		Routine	Fioutino	1	Routine	Routine		Routino	Routine
Nab-paelitaxel administration, including pre-medication		Routine	Routine	Routine	Routine	Routine	Routine	Routine	Reutine	Routine	Routine
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ON-PROCEDURE COSTS		and the second second	The second second second	States and	and the second	and the second second		the second second			Section and the
vestigator	\$175	\$175	\$175	\$175	\$175	\$175	\$175	\$175	\$175	\$175	\$176
tudy CoordinatonNurse	\$53	\$53	\$53	\$53	553	\$83	\$53	\$53	\$53	853	853
ata Management	\$30	\$30	\$30	\$30	\$30	\$30	\$30	\$30	\$30	93.0	\$30
otal Cost Per Subject	\$1,032.09	\$3,497.00	\$519,51	\$549,61	\$747.00	\$489.51	\$549.51	\$3,497.00	\$519.51	\$549.51	\$747.00
verhead Costs (25%)	\$258.00	\$874.00	\$130,00	\$137.00	\$187.00	\$122.00	\$137.00	\$874.00	\$130.00	\$137.00	\$187.00
otal Cost per Visit including Overhead	\$1,290.09	\$4,371.00	\$649.51	\$686.51	\$934.00	\$611.51	\$686.51	\$4,371.00	\$649.51	\$686.51	\$934.00
and Cost one Subject fall (falls) leads free Cost and full	** *** ***										
otal Cost per Subject (all visits) including Overhead (15 cycles) otal Cost per Subject including Overhead	\$1,290.09 \$60,201.50	\$4,371.00	\$649.51	\$686.51	\$934.00	\$611.51	\$685.51	\$4,371,00	\$649,51	\$685.51	\$934.00

Subject ID	Description	Price per CTA Exhibit	Quantity	Amount	
21-0000	Cycle 2; Day 8 (+/- 3)	•		s -	
	Concomitant Meds	27.00	1	27.00	
	Vital Signs	12.51	1	12.51	
	Hematology	11.00	1	11.00	
	Serum Chemistry	12.00	1	12.00	
	Magnesium and Phosphorus	10.00	1	10.00	
	Adverse Events	159.00	1	159.00	
	Investigator	175.00	1	175.00	1
	Study Coordinator/Nurs <mark>e * (see n</mark> ote on justification ta	53.00	0	0.00	
	Data Management Pagg Overhead Costs (25%)		1	30.00	
	Total per CTA exhibit	611.51			
	Total Invoice	[Line is formula driven]		\$558.51	
	rtify to the best of my knowledge and belief that the report is true, c ipts are for the purposes and objectives set forth in the terms and co			s, Windows Use Notice this amo the CTA exhibit form will need t	unt is less tha t. A Justificat

Example of Justification for Discrepancy b/w CTA Exhibit and Invoiced Amount

Example

Justification Form for discrepancy between Exhibit/Table on CTA and Invoice

Project number: Example Invoice:

 Subject ID
 Description
 Exhibit/Table Amount
 Invoiced Amount
 Justification for discrepancy.

 21-0000
 Study Nurse/Coordinator
 \$53.00
 \$0.00
 The study coordinator/nurse was not present on the day the subject came to clinic to complete his cycle 3, day \$ visit; therefore, the department can not bill the sponsor for her time.

+* Ali values are subject to verification and adjustments. **

Balance and Transaction Report - Summary and Detail

Transaction Date	10/21/2021				Prior Day
Tran. Date Value Date	Description	Customer Ref.	Bank Ref.	Credit Amount	Report Time (ET)
XXXXXXXXX XXXXXXXXX	EFT CREDIT	000250000009821	2949420041TC	XXXXXXXX	04:32 AM
	ORIG CO NAME:	BMSQUIBB			
	ORIG ID:	1220796415			
	DESC DATE:	211020			
	ENTRY DESCR:	PAYMENTS			
	ENTRY CLASS:	CTX			
	TRACE NO:	021000029420041			
	ENTRY DATE:	211021			
	IND ID NO:	000250000009821			
	IND NAME:	0009LOUISIANA STATE			
	ORIG BANK:	JPMorgan Chase Bank, N.A. (NY)			
	Addenda:	ISA*00* *00* *01*001288497F *0 5*U*00401*00001801*0*P*>\GS*RA*0012884 \ST*820*000002129\BPR*D*240000*C*ACH*C		1605*1801*X*004010	

Invoice Status

Billing and Accounts Receivable website has invoice status available for review

Information can be sorted by Project, Invoice and Bill To Sponsor



HSC Invoice and A/R History <mark>of 11/18/21</mark>															
Name	Ŧ	Bill Tc 🔻	Project 💌	PO Ref	-	Invoice	-	From 💌	То	-	Inv Amt	-	Item Balance 🔻	Acctg Da 👻	Dt Invoic

Clin Card

Clin Card Set Up : Clin Card Setup form is located on our website: https://www.lsuhsc.edu/administration/accounting/clincard.aspx

Please complete form and send to : <u>Nosponproj@lsuhsc.edu</u>

Information Needed:

- Peoplesoft Chart string
- Study Title
- PI name
- IRB#
- Study coordinators name, e-mail address and phone number (a person can not be a coordinator and approver)
- Study approvers name, e-mail address and phone number (a person can not be a coordinator and approver)
- Payment structure per visit and payment amount per visit

Example of ClinCard Set Up Request

Department:			-	Study ID /Project numbe	r			-			
Chartstring: Sponsor:											
Study Title :										-	
Study Hue .										-8	
PI Name :	1 <u>21</u>		PI E-Mail		_		PI Phone			-	
IRB#:			-								
IRB Protocol Title (if different from study title) :						-					
Site Data:								0.1			D U
Site Name LSU Health Sciences Cente	Site #/ID	Address Line 1	Address Line 2	City	State/ Province	Postal Code	Country	Site Phone #	PI Title	PI First Name	PI Last Name
Study Coordin	nator and Approvers										
Site #/ID	First Name	Last Name	Title	Email Address	Phone Number	Study Coordinator	Approver	Views Reports	Maintains Studies		
Department #	James (Example)	Doe	Coodinator	jamed@xxxxx	X0X-X0X-X00X	Yes	No	No	SPA		
									SPA SPA SPA SPA SPA		
				" should be marked "Yes".					C. M		
Note: A study coo	rdinator cannot be an app	prover. Both roles mus	st be segregated								
Payment Stru	cture:										
Visit Name	Payment Amount	Participant ID Required (Y/N)	SSN Required								
Initial visit	\$60.0	ργ	Y	(Example)							
8 week visit	\$25.00	1	1	(Example)							

Clin Card Continued

https://www.lsuhsc.edu/administration/accounting/clincard.aspx

Request for Blank Clincards – Form is located on our website. Please complete form and send to: <u>Nosponproj@lsuhsc.edu</u> and Re: Blank clincard request and "Project Number"

Sponsored Projects will review and forward to Direct Pay for processing

When cards are available, Ms. Burlison will send you an e-mail stating the cards are ready for pick up

Should you have trouble trying to locate your study and/or getting into the Clincard system, please contact <u>NoSponProj@lsuhsc.edu</u> and Re: Request for Emergency ClinCard Assistance

Example of the Request for ClinCards



Date:

Person Requesting ClinCards:		
Department:		
Number of cards: Study ID/PeopleSoft Number:		
Department Signature:	Date:	
Sponsored Projects approval:	Date:	
Direct Pay approval date:		
ClinCards # range:		

LSUHSC picture ID is required when picking up ClinCards

ClinCards pickup address: 433 Bolivar Street Direct Pay – Attn: Danielle Burlison Room 615 New Orleans, LA 70112-2223

Section below is to be completed by person picking up ClinCards

Print name:

Signature:

Date:

Other ClinCard Items found on our website:

- ClinCard User Guide: Overall Version
- ClinCard User Guide: Site Coordinator
- ClinCard User Guide: Cardholder FAQ's

- Quick Reference Guide
- ClinCard Service Center Rates
- Policy Regarding Collection of Personal Identifiers for Paid Clinical Trial Participants

ClinCard Requirements for Participants

LSUHSC must comply with Subsection 6041 of the Internal Revenue Code. This requires a 1099 form to be generated for participants receiving payments in excess of \$600.00. This is a cumulative total for all clinical trials in which a participant may be enrolled at LSUHSC.

In order for a ClinCard to be issued to a study participant, the following is needed:

- Collection of personal identifiers for paid clinical trial participants
- Full name, valid address and social security number at the time the sponsored clinical trial participant signs the Informed Consent Form (ICF)
- The collection of a signature for each study participant who receives a ClinCard payment

Suggested ClinCard Reconciliation

Payments By Study Report: This report is generated from the ClinCard system. It compares the amounts that sponsored clinical trial participants were paid to the amounts established at the time of ClinCard study setup or at the time of subsequent ClinCard setup changes. It also compares those payments to the agreed-upon amounts, if any, specified in the CTA.

Transaction ID 💌	Study	Created By	Approved By	Stuc 🐣	Site Name	Card	Subject ID 🔻	Approval Date	Transaction Date	Trans Typ	Description	Amount	Approval
156415079744	All of Us Network	XXXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-03 15:27:54	2021-11-03 15:27:55	ADD FUNDS	Initial: 25.00 USD	25.00	
156415146736	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-08 14:50:19	2021-11-08 14:50:20	ADD FUNDS	Initial: 25.00 USD	25.00	
156415146737	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-08 14:50:19	2021-11-08 14:50:20	ADD FUNDS	Initial: 25.00 USD	25.00	
156415164653	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-09 15:22:17	2021-11-09 15:22:18	ADD FUNDS	Initial: 25.00 USD	25.00	
156415164655	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-09 15:22:17	2021-11-09 15:22:18	ADD FUNDS	Initial: 25.00 USD	25.00	
156415164654	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-09 15:22:17	2021-11-09 15:22:18	ADD FUNDS	Initial: 25.00 USD	25.00	
156415403488	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-16 10:37:23	2021-11-16 10:37:25	ADD FUNDS	Initial: 25.00 USD	25.00	
156415403489	All of Us Network	XXXX	XXXXXX		x00000X	XXXXXX	XXXXXXXX	2021-11-16 10:37:23	2021-11-16 10:37:24	ADD FUNDS	Initial: 25.00 USD	25.00	
156415411043	All of Us Network	XXXX	XXXXXX		x00000X	XXXXXX	XXXXXXXX	2021-11-16 16:04:58	2021-11-16 16:04:59	ADD FUNDS	Miscellaneous Payment: 25.00	U 25.00	
156415454895	All of Us Network	XXXXX	XXXXXX		X00000X	xxxxxx	XXXXXXXX	2021-11-19 08:04:08	2021-11-19 08:04:09	ADD FUNDS	Initial: 25.00 USD	25.00	
156415454896	All of Us Network	XXXXX	XXXXXX		XXXXXXXX	xxxxxx	xxxxxxx	2021-11-19 08:04:08	2021-11-19 08:04:10	ADD FUNDS	Initial: 25.00 USD	25.00	
156415454897	All of Us Network	XXXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-19 08:04:09	2021-11-19 08:04:10	ADD FUNDS	Initial: 25.00 USD	25.00	
156415458214	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-19 10:38:19	2021-11-19 10:38:39	ADD FUNDS	Initial: 25.00 USD	25.00	
156415462145	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-19 12:18:27	2021-11-19 12:18:29	ADD FUNDS	Initial: 25.00 USD	25.00	
156415470874	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-19 15:06:42	2021-11-19 15:06:43	ADD FUNDS	Initial: 25.00 USD	25.00	
156415487536	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-22 11:52:02	2021-11-22 11:52:03	ADD FUNDS	Initial: 25.00 USD	25.00	
156415568109	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-29 12:27:51	2021-11-29 12:27:52	ADD FUNDS	Initial: 25.00 USD	25.00	
156415591310	All of Us Network	XXXX	XXXXXX		xxxxxxx	XXXXXX	XXXXXXXX	2021-11-30 13:57:33	2021-11-30 13:57:34	ADD FUNDS	Initial: 25.00 USD	25.00	
156415591311	All of Us Network	XXXXX	xxxxxx		X00000X	XXXXXX	XXXXXXXX	2021-11-30 13:57:33	2021-11-30 13:57:34	ADD FUNDS	Initial: 25.00 USD	25.00	

ClinCard Expenditures Posted to the Project

Monthly journal entries for ClinCard are processed by SPA. These expenditures can be found on your ledgers usually a month after the expense occurred.

GL	Posted								Ехр							
Uni 👻	Date 🔻	Ye	Peric 🗐 Accou 🗐	Fur 🔻	Dep 🔻	Prc 🔻	Clas 🔻	Project 🔻	Amoui 🔻		Line Description	-	Payee Name	🔻 Payee I 🔻	Journal II 🚽	PO
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXX	25.00	EX0169					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	X00000X	25.00	EX0169					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXX	10001	20200	XXXXXXX	25.00	EX0027					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXX	10001	20200	XXXXXXX	25.00	EX0169					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXX	10001	20200	XXXXXXX	25.00	CX1062					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXX	10001	20200	XXXXXXX	25.00	EX0177					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0169					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0167					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	X00000X	25.00	CX1062					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0027					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	X00000X	25.00	EX0027					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113				X00000X	25.00	CX1062					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0180					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0169					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0177					JESP022036	
LSUNO	2021-10-20	2,022	4 533035	113	XXXXXX	10001	20200	XXXXXXX	25.00	EX0177					JESP022036	
LSUNO	2021-10-20	2,022	4 537800	113	XXXXXX	10001	20200	XXXXXXX	36.00	Clincard I	nitial Fee 09/2021				JESP022035	
LSUNO	2021-10-20	2,022	4 537800	113	XXXXXX	10001	20200	xxxxxx	35.28	Clincard L	.oad Fee 09/2021				JESP022035	
LSUNO	2021-10-20	2,022	4 537800	113	XXXXXX	10001	20200	xxxxxx	10.35	Clincard L	icense Fee 09/2021				JESP022035	

Concluded Clinical Trials

Departments will submit a Sponsored Agreement Closeout Request Form with appropriate signatures to <u>Nosponproj@lsuhsc.edu</u>

Departments should make sure of the following:

- The sponsored agreement is complete
- All deliverables contained in the agreement have been completed
- All financial and performance obligations are complete

Departments should review the following:

- Revenues and expenditures for accuracy
- Outstanding AR for any outstanding invoices
- Identify if the project has a surplus or deficit that needs to close to a residual balance
- Complete the Sponsored Agreement Closeout Certification form

Clinical Trails Closed to Residual Balance

Before funds can be transferred to a residual balance account, agreements need to be reviewed to see if unexpended funds need to be returned to the sponsoring agency and/or if any restriction has been placed on the funds that would not allow for this transaction to take place.

Please note that indirect costs will be applied to any residual surplus or deficit using the rates in effect for each individual clinical trial. SPA will process this journal entry at the time of closeout.

EXCEPTION: Indirect costs will not be applied on Federal grants and contracts that are reported on the Schedule of Federal Expenditures (Schedule 8 - SEFA). These are not true indirect costs within the context of OMB A-21 and these costs should not be reported on the Schedule of Federal Expenditures.