

ClinCard at Rutgers

Overview for Study Teams





Agenda

- Overview of ClinCard @ Rutgers, including current fees, roles/responsibilities
- Tax compliance
- Additional program features
- Informed consent process
- How to request that a new study be set up
- Funds reconciliation process

Purpose of ClinCard Program:

- Electronic debit-card system for research subject payments or reimbursements, or recurrent payments of other types
- Web-based system to register a clinical research study, enter study subjects and authorize payments

Transition from MasterCard to Visa @ Rutgers

- As of March 1, 2024, all new studies have been set up using ClinCard Visa cards
- Older studies set up on MasterCard continue to use MasterCard

ClinCard Platform

- Visa and Mastercard studies appear in the same list on the ClinCard website.
- Visa studies are prefixed with "Visa".



"VISA" is added before the study nickname

ClinCard offers an ability to make payments as well as reimbursements

- Payments: set/pre-determined milestone payments to participants (examples: for attendance at scheduled study visits or for completing required questionnaires.) Payments are taxable income.
- Reimbursements: Direct reimbursements for travel (i.e. mileage, parking, tolls, ride share, air travel, hotel), or other expenses, such as medications. Not considered taxable income as long as accompanied by receipt (although no receipt required for mileage.)

Fee Schedule – As of January 1, 2024 (applies to both MasterCard and Visa)

Fee	Current Cost	Change	Frequency	
Physical Card Assignment	\$4.00	+\$0.05	Initial Issuance Lost Card (if study chooses)	
Virtual Card Assignment	\$2.50		Initial Issuance Lost Card (if study chooses)	
Card Load	\$3.95	+\$2.80	Each time a card is loaded with money (reimbursement or milestone payment)	
TIN Validation*	\$1.00		Per subject / 1 time only	
Rideshare Admin Fee**	\$3.00		Per ride scheduled by study team.	
Lost Card (participant)	\$7.00	No Change	Per replacement – taken from balance of card.	
Inactivity (participant)	\$4.50/month	No Change	After 6 months of no activity – taken from balance of card.	

^{*}TIN Validation only if study design meets threshold for taxable withholding per university policy.

^{**}Optional service able to be used by study team.



RUTGERS CLINCARD POLICY HIGHLIGHTS

Rutgers Health Clinical Trials Office (CTO)

- "Owner" and Host of system
- Responsible for setting up new projects, granting system access
- Purchases and receives debit cards from Greenphire and distributes to schools





Rutgers Health CTO

- Generates reports from system (including a monthly report of all ClinCard expenses by study for the purposes of financial reconciliation)
- Generates and shares with Rutgers Tax office reports of recipients earning more than \$600 annually and to whom the Tax Office will issue 1099 forms for income tax compliance





Schools and Units outside of Rutgers Health (Non-Oncology) must designate*

- A ClinCard Point of Contact
- At least two "Approvers"
- At least one person who will take responsibility for funds reconciliation

(*Individuals may serve more than one role.)

ClinCard Point of Contact

- Primary point person for communications with CTO
- Maintains school or unit card inventory; anticipates card needs
- Helps to trouble-shoot local issues with the system before escalating to CTO
- Communicates with investigators & study coordinators about the availability of the system

Approvers

- As per policy approval is required for:
 - ☐ Payments greater than \$100
 - ☐ Manual (i.e. off schedule) payment
 - ☐ Travel or other reimbursements above the designated thresholds
- Should have at least two Approvers per school or unit
- Approvers cannot be the study team members making the payments
- Should have access to the contracts for the studies or other projects; i.e. business office or research administrators
- Note: For Rutgers Health Non-Oncology: The CTO ClinCard team serves as approvers by default, unless a study team or department requests otherwise.

Reimbursement thresholds for secondary approval

Туре	When Under		
Tolls/Parking	\$35.01		
Flights	Never Auto Approve		
Hotels/Accommodations	Never Auto Approve		
Rental Cars	Never Auto Approve		
Public Transit	\$35.01		
Taxi/Rideshare	\$75.01		
Meals/Food	\$50.01		
Medication	\$50.01		
Other	Never Auto Approve		

A note about the approval process

- Approvers are not e-mailed with a prompt to approve a payment in real time: Emails are sent only at 6:00 AM and 4:00 PM.
- Best practice is for the study coordinator to notify the approver whenever a payment requiring secondary approval is made.

Funds Reconciliation

- School or unit must designate one or two individuals to be responsible for monthly ClinCard charge reconciliation and transferring funds from the study project to the ClinCard funding account
- Designee must be able to submit and process journal entries through the university's Oracle financial management system

PI and Study Team responsibilities

- All new users must review the applicable information on the <u>Rutgers Health Clinical Trials Office ClinCard Information</u> <u>Portal</u>
- Provide all required information about the study to the CTO (via <u>REDCap form</u>) in order to set up a new study and make changes over the life of the study as needed

PI and Study Team responsibilities, cont'd

- Assure concordance between:
 - Study budget/contract
 - IRB application/consent
 - ClinCard study stipend schedule
- Educate study participants about the system and assure that they have specifically consented to using ClinCard prior to their first payment
- Assure funds are available in project account to cover costs of the payments dispersed
- Anticipate card needs and maintain accountability of cards received and dispensed to study subjects

TAX COMPLIANCE

Rutgers Policy & US Tax Law

- •Rutgers Policy: Study teams need to collect SSN if a participant has the possibility of earning \$300 or more in a calendar year OR if a single payment is \$100 or more (formerly \$75.00.) The CTO will configure the study in ClinCard accordingly.
- •In accordance with **IRS law**, the Rutgers Tax Office issues a 1099 to the participant if \$600 or more is earned in subject payments



Greenphire's Tax Functionality

- Consists of two separate features:
 - Real-time TIN/SSN validation within the portal
 - Backup withholding will be an option for participants who can't (or won't) provide an SSN
- Advantages:
 - Improve RU compliance with IRS regulations
 - Addresses the quandary of how to pay trial participants without an SSN or those who refuse to provide

TIN Validation

- CTO will turn this feature on or off for each study, depending on whether there are tax implications for the study (i.e. the participant has the potential to earn \$300 or more in payments or if any payment is \$100 or more.)
- There will be an error message if an invalid SSN/TIN is entered:



 $\begin{tabular}{ll} Welcome, test test \\ English & User Settings & Logout \\ \end{tabular}$

REGISTER PARTICIPANT

LOOK UP PARTICIPANT

SUPPORT

Taxes may be withheld from this payment. To stop taxes going forward, the study participant must provide their TIN. Please enter one <u>here</u>.

Tax Withholding

- For participants who fail TIN validation (either because they do not have an SSN or choose not to provide it), back-up withholding will kick in once they earn \$300 or more in a calendar year
- 24% of the stipend will automatically be withheld
- Rutgers will remit these funds to the IRS without any identifying information on the participant

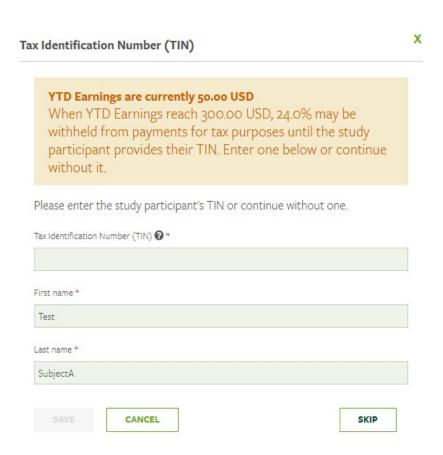


TIN Validation/Tax Withholding

 You will be able to see the amount withheld in the payment history tab of the participant.

Payment History						
SUBMITTED	AMOUNT	STUDY	DESCRIPTION	STATUS (1)	STATUS DETAILS	ACTIONS
26-JAN-2024 09:27 AM EST test test (ttest88)	1,000.00 USD	Rutgers Visa Card Test Study	Transaction: #A596563DDB2B4B57A537FD64E1A60B4C Miscellaneous Payment Milestone: Tax Withholding: 168.00 Released Amount: 832.00 Notes:1000 audit history test	Attempting to load	Approved: 26-JAN-2024 09:27 AM EST test test (ttest90)	-

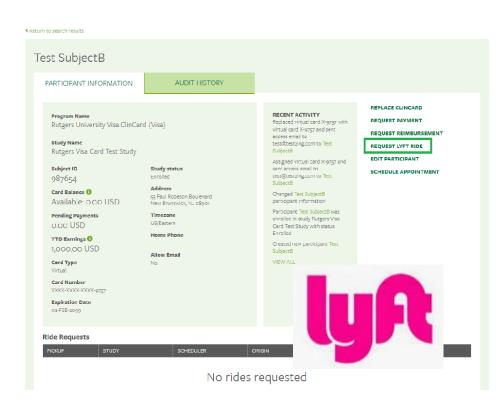
- TIN Validation/Tax
 Withholding
 - A reminder will appear if there is not a valid TIN which will indicate the YTD earnings.

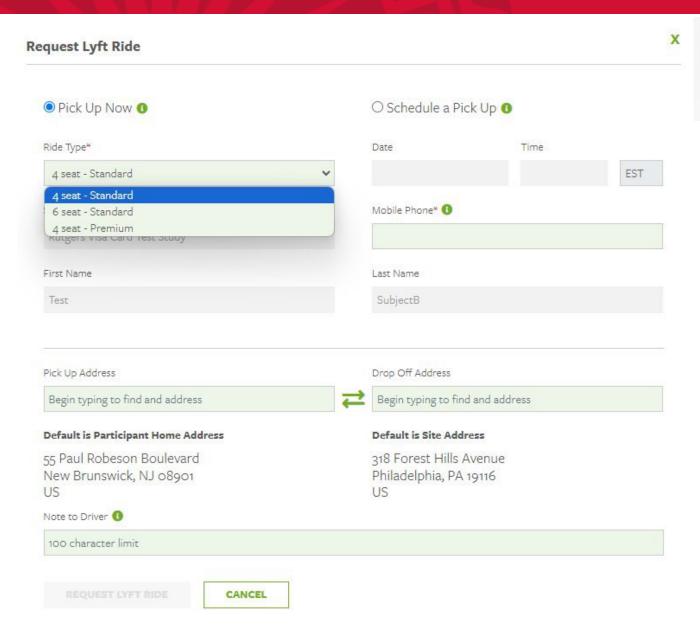


ADDITIONAL CLINCARD FEATURES

Lyft Integration

- Allows study teams to request a Lyft immediately or schedule a pickup for participants.
- The study will be billed for the ride + \$3 administrative fee, so be sure to use this only if budgeted (or agreed upon by sponsors).
- Must be included in the ICF (specific language is available in the HRPP Toolkit.)







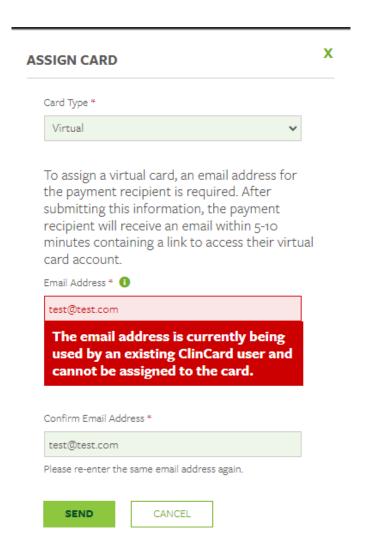
Lyft



- Will show up as an option for ALL studies regardless of whether it is allowed for that study
- Important to verify whether it is allowed for a study before offering to participants

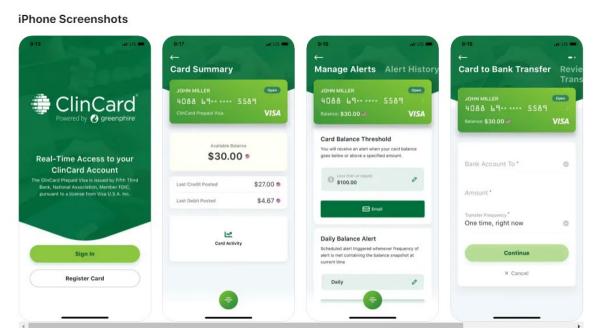
Visa Virtual Cards

- Allow study teams to email a participant a card as opposed to providing a physical card.
- Cost savings: Virtual cards cost \$2.50 each (as opposed to \$4.00 for plastic cards)
- Assigning a card requires you to enter the participant's email twice.



Other features for Visa Cards

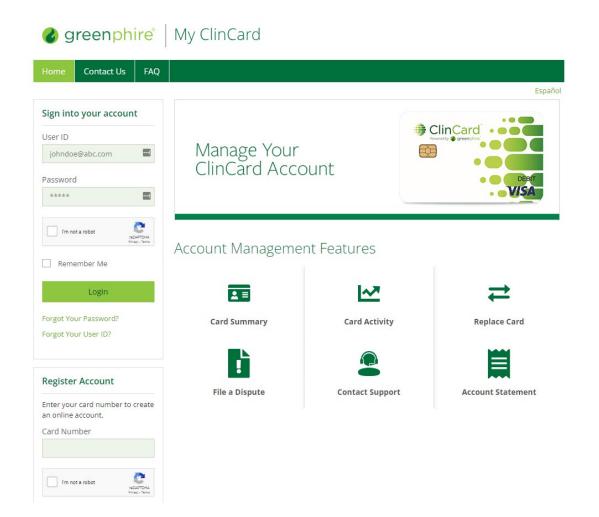
- For both virtual and plastic Visa Cards: Participants will have the ability to transfer funds from the card to their bank using a Card to Bank (C2B) Transfer.
- Participants can manage their card using a mobile app (iPhone & Android)
- All ClinCard prepaid Visa debit cards may be linked to a mobile wallet (i.e., Apple Pay, Google Pay, Samsung Pay), and then used at all merchants that accept Visa contactless payment





For more information on ClinCard Visa:

https://myclincard.mycardplace.com/cholder/welcome

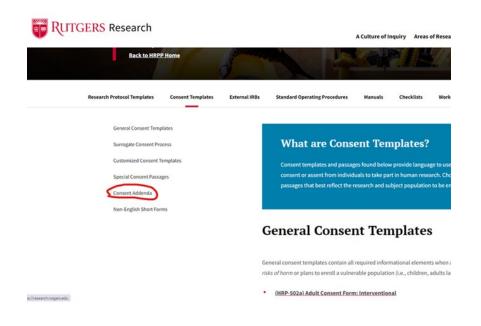


INFORMED CONSENT PROCESS

ClinCard Informed Consent Addenda are available in the HRPP toolkit

ClinCard recipients must consent to using ClinCard through either of two options:

- 1. Insert the Rutgers-approved template language related to ClinCard in the payments section of the main study informed consent form
- 2. Administer the "stand-alone" ClinCard consent.



Insert applicable language based on tax implications, use of Lyft, etc.

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ADDENDUM: CONSENT/AUTHORIZATION FOR PARTICIPATION IN THE CLINCARD PROGRAM

Insert the below language into your main consent form under the section titled "WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?". Replace instructional language (in BLUE) with language that applies to your <u>research</u>

In order to compensate you for your time and effort in participating in this study, you will be paid \$xx for each visit that you complete, according to the schedule below *Add or delete as appropriate* for a total of \$xxx.

(Insert table showing visits and amount paid if the amount is different at each visit/milestone.)

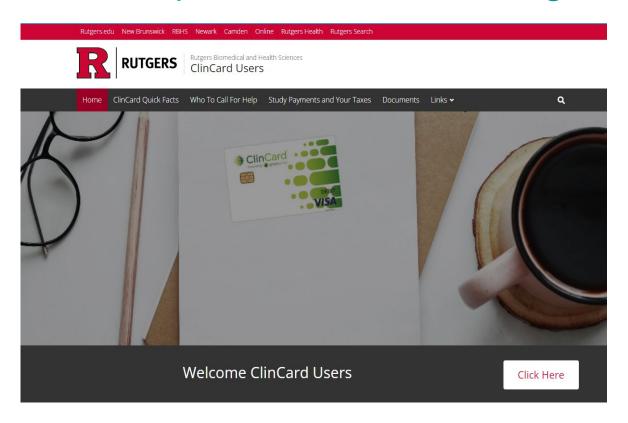
If using ClinCard, insert this:

Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You

Parental Consent for pediatric studies using ClinCard

- Notes that the card will be assigned to the parent/guardian.
- Parent or guardian's SSN will be used

Rutgers Participant-facing website https://clincardusers.rutgers.edu/



This URL is provided to participants within the new template consent language

Additional terms and conditions related to using ClinCard

- No cards (either Visa or MasterCard) may be issued to anyone under the age of 18. The Visa platform will not allow you to enter a DOB under 18 years of age.
 - Cards are assigned to a parent/guardian using their SSN
- If mailing a card: Insert the fully sealed Greenphire envelope inside another envelope before mailing
- Be sure to provide the participant with letter that the card is adhered to. (There should be no reason to open the envelope before presenting it to the subject.)

SETTING UP A NEW STUDY IN CLINCARD

Form link available on

CTO ClinCard portal

New Study Set-up request via RedCap form:

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THE STATE UNIVERSITY
OF NEW JERSEY



ClinCard Setup Request (Visa Platform)

Instructions:

Complete this form to request that the Clinical Trials Office set up a clinical research study in the ClinCard system in order for research participants to be paid for milestone study visits or reimbursed for expenses via electronic debit card. To complete this form, you will need:

- Basic Study Information
- . The finalized contract/budget information, including total study budget for reimbursement and stipend payment.
- The Oracle Project number assigned to the project by Grant and Contract Accounting and your unit's UDO string.
- · Rutgers eIRB number
- . IRB approved consent form (to verify that the IRB has approved the payment amount and schedule)
- · A completed excel schedule of events for study payments:
 - o Download Excel template
- Excel list of individuals authorized to make subject payments for this study and the list of approvers authorized by your school or unit for this study.
 - o Download Excel template

Please direct any questions you may have to clincard@rbhs.rutgers.edu.

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General Information		
Today's Date * must provide value	2024-03-27 🛅 Y-M-D	
Submitter Name (Your Name) * must provide value		≜
Submitter's Email * must provide value		
Departmental Information		

ClinCard Study Set-up Request

To complete the form, you will need:

- Rutgers eIRB number
- Oracle Project number and UDO (Unit, Division, Organization) codes.
- Final study budget information regarding subject payments
- Final, IRB approved informed consent form for the study (note that the CTO will verify that the relevant information related to ClinCard has been included in the payments section, or that there is a plan in place to administer the stand-alone ClinCard consent form to participants.)

Study Naming Conventions for Visa ClinCard

 Study Name: Visa + Study Nickname + eIRB number (example: Visa REACT - Pro2024000957)

 Study ID: UDO - PI Last name – Oracle Project # (example: 84060852088 - Smith – 825674)



New Study Set-up request

 Fill out the study payment schedule of events (available as an excel attachment within the REDCap form) to note both milestone payments as well as reimbursements allowed as per the budget and ICF.

Study Short Title	•													T	
Rutgers eIRB Number:															
PI:															
		Subject Payment Schedule													
	example:	example:	example:												
Visit Schedule	Screening														
Visit seriedate	example:	buschine	WCCKZ												
Payment Amount	\$50.00														
· ·															
Salact what type of rain	mbursaments (if	any) will be	allowed	Note you	will be rec	uired to u	nload roco	ints into th	e ClinCard	wahsita ir	order for	any reimh	ursamant	OTUED the	n mileae
Select what type of reir			allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	n mileag
	mbursements (if	any) will be	e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	ın mileag
Meals/Food			e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	ın mileag
			allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	ın mileag
Meals/Food Tolls/Parking			allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	ın mileag
Meals/Food Tolls/Parking Mileage			e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	n mileag
Meals/Food Tolls/Parking Mileage Taxi/Rideshare			e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	n order for	any reimb	ursement	OTHER tha	n mileag
Meals/Food Tolls/Parking Mileage Taxi/Rideshare Flight			e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	n order for	any reimb	ursement	OTHER tha	n mileag
Meals/Food Tolls/Parking Mileage Taxi/Rideshare Flight Rental Car	Yes		e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	in mileag
Meals/Food	Yes		e allowed.	Note you	will be req	uired to u	pload rece	ipts into th	e ClinCard	website ir	order for	any reimb	ursement	OTHER tha	n mileag

Schedule of Events

- Be sure to name the visit in a manner that is consistent with the protocol study visits (i.e. screening, Week 4, etc.) and which will make sense to the study coordinator when he/she goes into the system to authorize a payment
- Beware of recurrent visits: The ClinCard system allows
 payment only once for each visit designated in the schedule.
 If the protocol schedule has recurrent payable visits (such as
 "repeat lab" visit, or "unscheduled visit" for adverse events) –
 put multiple visits into the excel schedule (i.e. repeat lab visit
 #1, repeat lab visit #2, etc.)

New Study Set-up request

Fill out the ClinCard User/Approver List (available as an excel attachment within the RedCap form)

- Designates the list of study staff who are authorized to make study payments for participants
- Denotes the school or unit ClinCard approvers designated for the study (send an send an inquiry to <u>clincard@rbhs.rutgers.edu</u> if you do not know who these individuals are.)

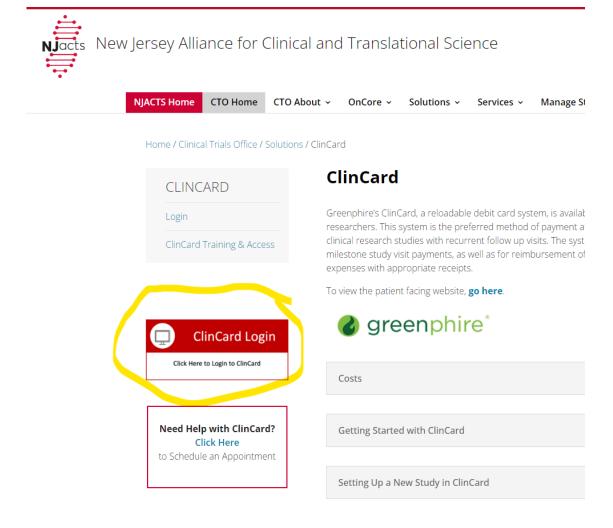
Study Short Title/Nickname:									
Rutgers eIRB Number:									
PI:									
ι	Jser & Approver Form		Form Version - 1.4 July 2023						
List of ClinCard Users Authorized to disperse study payments Use this space to report any changes in the user/app list following initial study set up. Email the revise ClinCard User and Approver list to the RBHS Clinical Office at clincard@rbhs.rutgers.edu									
Name of ClinCard User	Rutgers Email Address	Date Added to Study	Date Dropped From Study						
List of your school or unit ClinCard approvers for this study									
Name of ClinCard Approver	Rutgers Email Address	Date Added to Study	Date Dropped From Study						
Jonathan Carter	jonathan.carter@rutgers.edu	Do-Not-Remove	Do-Not-Remove						
Nancy Reilly	reillyna@rbhs.rutgers.edu	Do-Not-Remove	Do-Not-Remove						
<u> </u>									

Be sure to communicate any relevant changes during the course of the study to the CTO

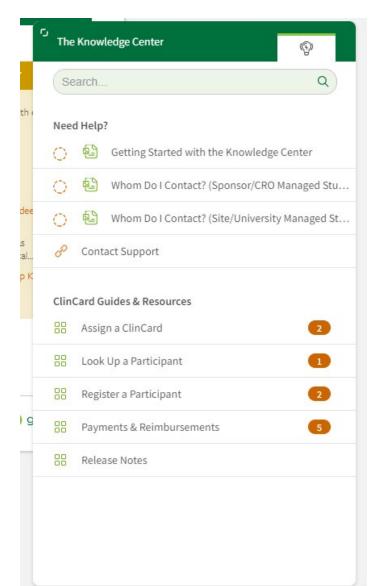
- As study staff are added or deleted from the study, you can inform the CTO by sending an updated User/Approver list for the study via e-mail to <u>clincard@rbhs.rutgers.edu</u>. Provide effective dates as applicable, and rename the excel file with the new date.
- Changes to the payment schedule of events can be made in a similar manner



Use Rutgers SSO from CTO website to access the platform



In-app Knowledge Center







CLINCARD RECONCILIATION WORKFLOW

Reconciliation Workflow

- Shortly after the month's end, the CTO designee will use the Program Balance Detail report and card inventory report to generate a breakdown of costs by study for each school/operating unit.
- This report will include all fees (i.e. stipends/reimbursements, card costs & upload fees.)

Monthly Report of ClinCard charges by study example

В		С	D	E		F		G	Н	
udy ID	Cł	arges	Total Transactions	Card Creations	Tr	ransaction Fees	Ca	rd Creation Fees	Subsidize	ed Fees
0545208528 - Panettieri - 203300	\$	69,750.00	2792	807	\$	3,210.80	\$	3,187.65		
0545208528 - Panettieri - 826192				1	\$	-	\$	3.95		
1566657632-Kinney-825383	\$	1,725.00	42	19	\$	48.30	\$	75.05		
5060851850-Kassotis-826236				1	\$	-	\$	3.95		
5060851850-Kassotis-826263	\$	200.00	2		\$	2.30	\$	-		
5062355574-Rosen-825110	\$	100.00	2	8	\$	2.30	\$	31.60		
50659657317-Steinberg-824335	\$	354.80	18	7	\$	20.70	\$	27.65		
4057955700-Pyrsopoulos-821088	\$	450.00	6	2	\$	6.90	\$	7.90		
4060852088 - Nyaku - 825674	\$	125.00	5	1	\$	5.75	\$	3.95	\$	9.70
4060852088 - Swaminathan - 812777	\$	25.00	1	1	\$	1.15	\$	3.95	\$	5.10
4060852088-Swaminathan-821753	\$	25.00	1	1	\$	1.15	\$	3.95	\$	5.10
4060852088-Chew-812777	Ś	120.00	4	2	Ś	4.60	Ś	7.90	Ś	12.50

Reconciliation process

- The designated individual at each school/operating unit will remain responsible for performing journal entries for studies conducted at their locations.
- The expectation is that these journal entries will be completed by the end of the following month (i.e. June ClinCard charges will be reconciled by the end of July.)

ClinCard @ Rutgers Health

- General e-mail inquiries about ClinCard may be directed to: clincard@rbhs.rutgers.edu
- Additional Contact Information:

Jonathan Carter jonathan.carter@rutgers.edu

Rebecca Freiday rfreiday@rbhs.rutgers.edu

Nancy Reilly reillyna@rutgers.edu

Sofia Shyprykevych sofiia.shyprykevych@rutgers.edu

School/unit contacts for disbursement of ClinCards

School/Unit	Contacts	Email	Telephone
RWJMS	Sherri Gzemski	gzemsksa@rwjms.rutgers.edu	732-235-6135
	Sylvia Rodrigo	rodrigmg@rwjms.rutgers.edu	732-235-6402
NJMS	Yanille Taveras	taveraya@njms.rutgers.edu	973-972-6262
	Chantey Roberts	cpr91@njms.rutgers.edu	973-972-4108
CINJ	Joseph Blay Christian Misdary	jb1369@cinj.rutgers.edu cm1344@cinj.rutgers.edu	732-235-7556

Thank you!

