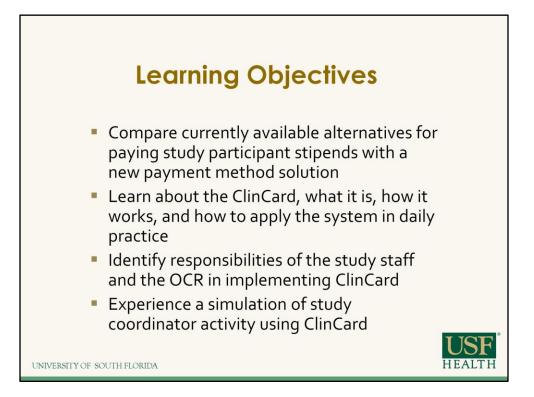


Catherine Jahrsdorfer, R.N., B.S.N. Director of Clinical Services Office of Clinical Research April 5 & 6, 2012



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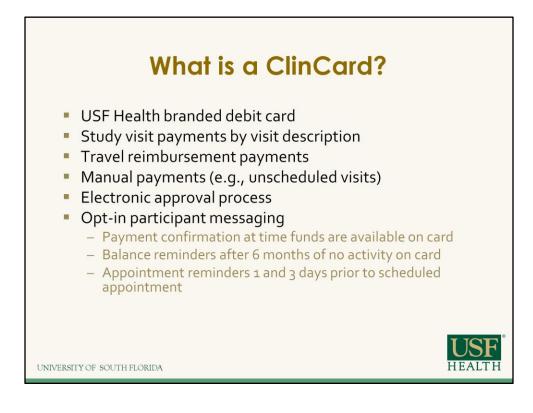
Talking Point: All of these participant stipend methods are governed by CCHIP 17 – Accounting for Payments to Research Study Subjects.

These alternatives can be labor intensive, time consuming = a true cost to USF, takes a long time for checks to get cut, variations between Departments and Divisions on how these get processed....

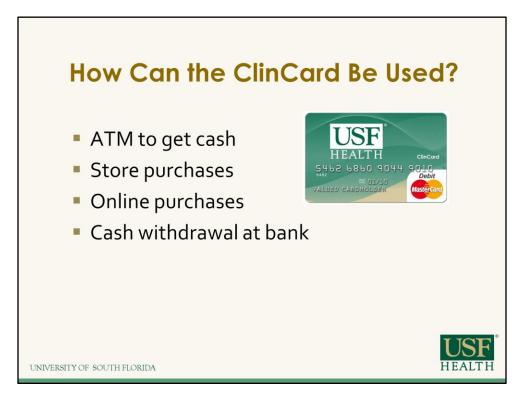


Scope of the ClinCard today is for Morsani COM non-Federally sponsored clinical research studies that provide participant stipends and travel reimbursements. The system is being implemented for studies running through the FAST accounting system. We are not opening up to Research Foundation/UMSA studies, aka "Banner Accounts".

If ClinCard is successful, may expand to other areas at USF in the future.



- A specially designed debit card for clinical research
- Allows study participants to receive payments electronically and access funds through various methods
- Participants can receive study related communications by email and text, although messaging is optional for each study participant

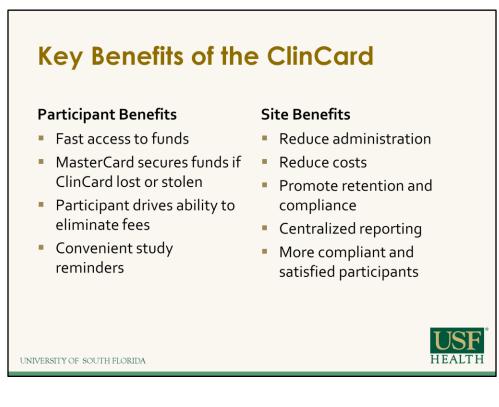


- Card is activated upon first payment load
- Activated card can be used immediately as a credit card
- ATM and cash back use requires a PIN be set up by study participant
- PIN set up information is located in the letter that is included in the envelope with the ClinCard (given when ClinCard is dispensed)

To use as a debit card to get cash back or at an ATM, a PIN must be set up by the study participant.

- Can call the toll free number on the back of the card
- Can reset by calling toll free # or going to MyClinCard.com
- ***NOTE We are getting Spanish language FAQs that we can distribute as needed***
- Store purchases, including a cash back option with no fee
- Online purchases
- Cash out a bank But don't have the participant surrender the card or a replacement will need to be provided!
- Gas purchases most gas stations place a hold on credit card purchases. Patients should be aware as this may limit the amount that they can access on the card until the hold is released (average gas hold is \$75 for 7 days).

• To avoid holds or declined purchases due to holds over the current limit on the card, the patient can advise the gas station or restaurant the amount that is currently loaded on the card and enter the payment amount.

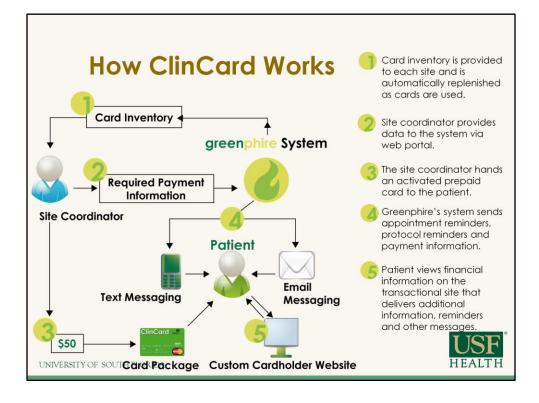


No fees for:

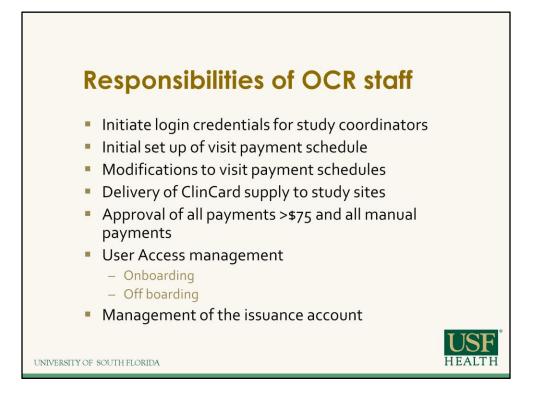
- Online or in-store purchases
- · Cashing out the card by presenting to a bank teller
- Calling automated system for balance inquiries
- Calling Customer Service and speaking to a live agent. Customer service agents do not know that the card holder is in a research study, just that they are a "Valued Customer" as illustrated on the image of the card in previous slide.
- Funds added by study team

The following will incur a fee:

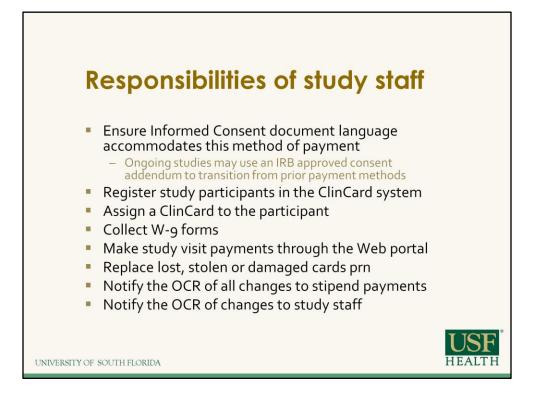
- Non-use for more than 6 months
- ATM withdrawals (fees vary by location) similar to when you use your debit card at a different bank.
- Request for a paper statement (can call or check online for free)
- Request for a replacement card through Customer Service (Study team can replace on-site at no charge to patient which is preferred)
- Request for a check through Customer Service to remove funds from the card



- Cards come in a legal size envelope with a cellophane display window through which the card # is visible.
- Site registers patient
- Site assigns card # at first visit and provides to the patient. This associates the card # to the patient.
- Patient receives communication once funds are available, plus additional communication if opts in for reminders
- Patient views their financial information on MyClinCard.com or by calling toll free customer service number



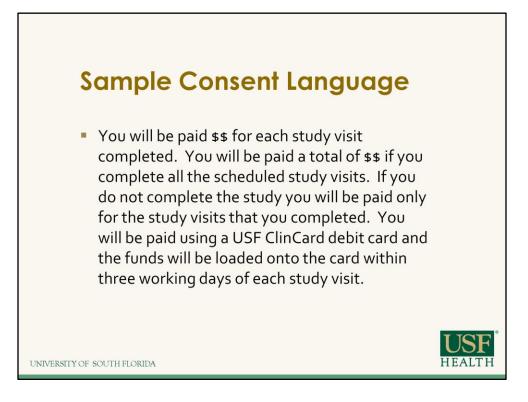
- You will receive your login credentials and a Quick Reference Guide via email
- Within the OCR we have separated duties so that the OCR team members who deliver cards to sites do not function in role of Approver
- OCR staff sets up the study in the system, including the \$ amount per visit
- Delivery of ClinCards are made in batches of 20



The W-9 is the source document for the information entered into the ClinCard system. W-9 should be collected and kept on file if cumulative payments are expected to exceed \$200/calendar year OR if a single payment exceeds \$50. The ClinCard system will generate a 1099 report for USF each year, therefore at Participant registration it is important to include SS#s.

Lost, stolen or damaged cards will automatically transfer the balance to the replacement card when the replacement card is assigned to the participant. It is a best practice for the site to replace a lost or stolen ClinCard for the study participant because if they request for themselves via Customer Service they will incur a fee.

The OCR must be informed immediately of employee terminations so that we can de-activate their user account immediately to limit potential for fraudulent activity.



Per HRPP Policy No 1003 Compensation to Human Research Subjects Section 6.1.6 "Compensation must be fully outlined in the informed consent document including prorated payments and total compensation as well as the method and timing of compensation"

Compensation Section of USF IRB IC template:

[IF COMPENSATION FOR PARTICIPATION IS AVAILABLE, include the dollar amount per visit and payment upon study completion of study activities. Explain any other costs you may be able to remunerate, such as parking fees, bus or taxi fare; childcare costs, or time away from work.]

You will be paid \underline{SS} if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid \underline{SS} for each complete study visit.

[USF investigators must include the following for studies where compensation is more than \$50 per payment or \$200 per calendar year. See Research CCHIP # 017 for more information.]

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.



Talking Point: How to Login to <u>www.clincard.com</u>

Go to www.clincard.com

Enter your login and password as provided to you. Keep in mind that your login and password are "case sensitive" so make sure your capital letters are in the correct place.

If you have difficulty logging into <u>www.clincard.com</u>, please click on the "Forgot username and password?" link, enter your email address and click "Reset my password." This will instantly send you an email with a link that allows you to reset your password.

Note: You can also call ClinCard's site support team at 215-609-4378

Register Subject	Look Up Subject Support		
Subject Registratio	n		
Subject ID*	Study* Study Status* Site* Test Study Enrolled Greenphire		Re
Name First Name*	Middle Last Name* Initials*		gis Pa
Address 1*			ister artic
Address 2			
City* Country* United States V	State* Zip Code*	Address should match that on participant's ID	a Study pant
Date Of Birth*	Subject Email		+ 2
ex: DD-MON-YYYY	ex: name@example.com		4
Subject Home Phone	Subject Cell		
ex: 215-555-1212	ex: 215-555-1212		
Email (Enable) Text I	lessaging (Enable)		

Talking Point: How to Register a Subject:

Login to <u>www.clincard.com</u>

Click on "Register Subject"

Enter the required information into the brief form

***Be sure to register the participant using the address that is on their ID in case they choose to make a card transaction that requires them to show ID

<u>Note</u>: If you would like the Subject to receive payment confirmations or appointment reminders, be sure the "Email (Enable)" and/or "Text Messaging (Enable)" checkboxes are selected Click on the "Register" button

You will be brought to the "Subject Information" screen which we will see in a moment where you can assign a card number, make a payment, schedule an appointment reminder, replace a ClinCard or edit a Subject's information If you have difficulty making a payment for the first time please call the ClinCard site support team at 215-609-4378 and they will be happy to walk you through it

	Look Up	o a Pa	rticipo	ant		
	ClinCard Admin][Portal Register Subject Look Up Su	bject Support		,	Welcome, Site Coordinator Edit Profile Change Passnood Loggud	
	Recent Activity No Recent Activity	Search Study - All Studies • Name: • Search	Subject ID:	Initials:		
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Talking Point: How to Look Up a Subject Who Has Already Been Registered:

Login to <u>www.clincard.com</u>

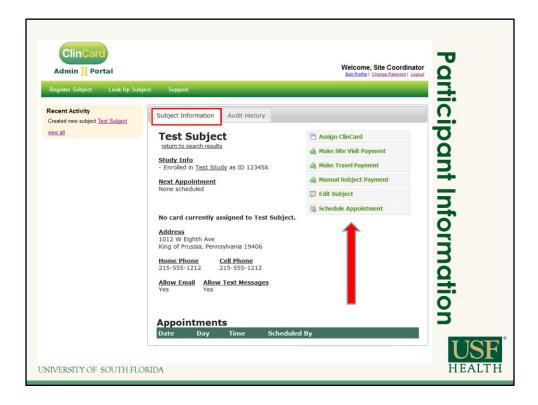
Click on "Look Up Subject"

Search for the Subject you want to pay by entering one of the following pieces of information and click on "Search"

- First name and/or last name
- Subject ID
- Subject's initials

Click on the underlined name of the Subject

You will be brought to the "Subject Information" screen where you can perform any of the actions required for the Subject, e.g., issue payment.



This is the "Subject Information" screen that was just just referenced. This is where you can assign a card number, make a payment, schedule an appointment reminder, replace a ClinCard or edit a Subject's information such as a change in address or opt in/opt out of messaging reminders. These activities will be discussed next.

ClinCard	I ClinCard	
Admin Portal Register Subject Look Up Subject Recent Activity Created new subject Test.Subject Merc all	Edit.Balle Chimae.Beenood Loadud	USF
UNIVERSITY OF SOUTH FLORIDA		HEALTH

Talking Point: How to Assign a ClinCard to a Subject:

Click on "Assign ClinCard" and a pop-up screen will appear

In the "New Card" field, enter the 16 digit number visible through the window of one of the ClinCard card packages you received

<u>Note</u>: There is no need to open the envelope prior to providing to the Subject Click on the "Assign" button

Once the card has successfully been assigned, you will receive a confirmation message at the top of the "Subject Information" screen

Now an option to "Replace ClinCard" appears. In the event that a Subject loses their card, you can replace that card for them by clicking on "Replace ClinCard," and follow the steps above, using a card number from a new ClinCard card package

Note: This will inactivate the lost card and automatically transfer any

available/pending balance to the newly assigned ClinCard

Make a	Site Visit Payment	
Register Solder Lock Up Subject Recent Activity Crasted new subject Test Subject stern all Stern all		USF
UNIVERSITY OF SOUTH FLORIDA		HEALTH

Talking Point: All Payments >\$75 require OCR approval. We will turn these around within 3 business days. Turn around is usually same day, but we need to accommodate enrollments that occur overnight and on weekends.

How to Make a Site Visit Payment:

Click on "Make Site Visit Payment" and a pop-up screen will appear

Select from the dropdown box which milestone the patient is being paid, e.g., Visit 1, Visit 2, etc.

Click on the "Pay" button

Once the payment has successfully been requested the "Pending Payment" area of the "Subject Information" screen will reflect the payment. It will also be reflected in your "Recent Activity" on the left-hand side of the screen.

Once a payment request has been approved and processed, the amount will be removed from the "Pending Payment" area and reflected in the "Available Balance" area

If the Subject has opted to receive email and/or text messages, the Subject will receive a payment confirmation communication when the payment is made

Make a	Travel Payment	
Register Subject Desk Desk Recent Activity Created new subject Test Subject Status	Augent Subject Information Audit History Assign Card wissign CinCard Turrent Card: wise Site Visit Payment New Card: Hase Site Visit Payment Mase Tarved Payment Hase Tarved Payment Mase Tarved Payment Hase Tarved Payment Mase Tarved Payment Hassign Cancel New Card: Hassign Cancel New Card: Hassign Cancel New Card: Hassign Cancel Status Hassign Cancel New Card: Hassign Cancel New Card: Hassign Cancel Status Hassign Cancel	
UNIVERSITY OF SOUTH FLORIDA		HEALTH

Talking Point: How to Make a Travel Payment:

Click on "Make Travel Payment" and you will be brought to a new page that will give you 3 travel reimbursement options:

Drive (calculates the appropriate amount to reimburse a patient for miles driven to/from appt) The system has been pre-loaded with the State of Florida's mileage rate of \$0.445.

Flight

Other

Enter the required information into the fields that will appear in the pop-up window Click on the "Save" button

When you are finished making payment requests click on the "Submit Request" button

NOTE: We are strongly encouraging sites to roll travel into the patient stipend as a lump sum to avoid the requirement to use the FAST Travel Module for patients. Work with your Project Liaison during budget development to achieve this.

Make ClinCard Admin [Portal	a Manual Payment	
Register Subject to Recent Activity Created new subject <u>Test Six</u> term all	Studylect Information Audt: History Studylect Information Studylect Information </td <td></td>	
UNIVERSITY OF SOUTH FLORIDA		HEALTH

Talking Point: All Manual Payments require OCR approval. We will turn these around within 3 business days. Turn around is usually same day, but we need to accommodate enrollments that occur overnight and on weekends.

How to Make a "Manual Subject Payment:"

Click on "Manual Subject Payment" and a pop-up screen will appear Enter the payment value that you want to pay to the Subject in the "Amount" field Add an appropriate comment in the "Note" field, e.g., Unscheduled Visit, Week 32, etc.

Click on the "Pay" button

Once a payment request has been processed, the amount will be removed from the "Pending Payment" area and reflected in the "Available Balance" area If the Subject has opted to receive email and/or text messages, the Subject will receive a payment confirmation communication when the payment is made



Talking Point: How to Enter a Subject into a Different Study:

You do <u>not</u> need to re-register or assign a new card to an existing subject if they are moving onto another study. Rather, you will select the existing Subject and be brought to the "Subject Information" screen. On the right hand side of the screen, you will see options that represent all of the actions you can perform on the Subject.

Click on the "Edit Subject" button

Click on the "Study" drop-down field and select the appropriate "new" study Enter an updated "Subject ID" in the text field if applicable Click on the "Save" button

<u>Note</u>: If the patient no longer has their ClinCard from the previous study, you can replace it for them (see

"How to Assign a ClinCard" steps).

S	ClinCard Admin][Portal	ppointment	Reminder Welcome, Site Coordinator
	Regenter Subject Look Up Subject Recent Activity Created new subject <u>Test Subject</u> View all	Subject Information Audit History Assign Card x Assign Current Card: None Assigned Malk New Card: Malk No card currently assigned to Test Subject. Assign Cancel Sch No card currently assigned to Test Subject. Address King of Prussa, Pennsylvania 19406 Home Phone Cell Phone 215-555-1212 205-551-212 Allow Text Messages Yes Yes	sign ClinCard ke Site Visit Payment ke K Travel Payment nual Subject It Subject
UNIVERSITY OF	SOUTH FLORIDA	Appointments Date Day Time Scheduled By	USF

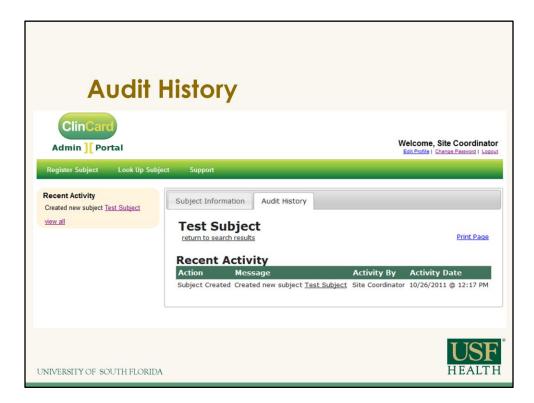
Talking Point: How to Setup an Appointment Reminder:

Click on the "Schedule Appointment" button and a pop-up menu will appear Using the dropdowns, enter the correct date and time of the Subject's next appointment

Click on the "Schedule" button

The appointment has been stored and will appear at the bottom of the "Subject Information" screen under the header "Appointments"

If the Subject has opted to receive email and/or text messages, the Subject will receive a reminder communication 3 days and 1 day prior to the Subject's next appointment



On this screen you will see all recent activity related to that participant.

Support		
ClinCard Admin [Portal	Welcome, Site Coordinator	
Register Subject Look Up Subject Support For immediate help please call (215-609-4378) between 8:30 AM and 8:30 PM Eastern Time, Monday - F		
Please enter a detailed description of your issue to help us resolve it quickly. Thank you. From: Site Coordinator Subject:		
Request/Comment:		
Send		TIOT
UNIVERSITY OF SOUTH FLORIDA		USF HEALTH

Talking Point: How to Get Help:

If you have questions about using the <u>www.clincard.com</u>, how it has been set up for your studies, or you have any other questions or comments you may reach the ClinCard site support team by:

Submitting an email request through the "Support" link within the <u>www.clincard.com</u> website

Directly emailing support@greenphire.com

Calling the site support team directly at 215-609-4378 between the hours of 8:30 am and 8:30 pm Eastern Time (Monday through Friday) in order to speak with a ClinCard support person

***You can also call the OCR - 813-974-3336 - and Liz will assist or refer you to one of the other members of the team.



Talk to your Project Liaison or call/email OCR if you are eager to jump into the queue to implement the ClinCard system for your studies.

