

## Joint Clinical Trials Office (JCTO)

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SOP Name: Weill Cornell Medicine/New York-Presbyterian ClinCard SOP  
Date Implemented: March 6, 2015

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Please also view the ClinCard User companion guides located on the JCTO website under Researcher's Toolbox

### 1.0 SCOPE

- 1.1 WCM/NYP studies identified as eligible to use the Greenphire ClinCard system for subject compensation including stipends and reimbursement for travel.

### 2.0 PURPOSE

- 2.1 This standard-operating-procedure (SOP) guide covers the implementation and use of the ClinCard system for subject compensation.

### 3.0 DEFINITIONS

- 3.1 User types and access rights:

ClinCard Site Coordinator - User that is authorized to register subjects in the ClinCard system, opt-in subjects for messaging\*, assign/replace ClinCards and distribute to subjects, request and/or load payments onto ClinCards, and schedule appointment reminders for subjects opted-in for messaging\*. The user is restricted to viewing subjects registered to the site in which they are associated and to the studies they are assigned. ClinCard may be used on multiple projects both with WCM as well as outside sponsors. Users should verify respective study(s) site upon logging into the system.

ClinCard Approver – User that is authorized to view pending manual and travel payment requests and approve / decline them as necessary. Once approved, payments are loaded onto subject ClinCard.

ClinCard Report Viewer - User that is authorized to view “on demand” reports available in the ClinCard system, including 1099 report which allows for viewing subject profiles / information.

ClinCard Admin User - User that is authorized to add studies, edit current studies, maintain study payments, and maintain user roles associated with each study in the system. This user cannot manage payments or look up (or see) subject profiles / information.

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ClinCard Super User – User that is authorized to do all of the above, as well as manage / assign users.

*\*Of Note: Not utilizing during current phase*

### 3.2 Subject compensation types:

Site Visit Payments (Stipends) – a pre-set payment that allows the user to select one of the below options on a per subject and visit basis. Once a payment is requested for a particular visit, that visit is removed as an option from the drop-down box and cannot be reselected for that subject. Site visit payments / stipends are approved automatically and are not subject to additional levels of approval. To process stipends/site visit payments the study visits must be built in the system (two parts). See Admin User Guide for instructions under “maintain study payments.”

Manual Payments – in the event a user must request a payment outside of the above option, this payment type allows a free-form amount to be entered along with a required note explaining the reason. All “manual” payments will require a designated approver to review and approve in the ClinCard system prior to payment being initiated.

Travel Reimbursement – if a subject needs to receive reimbursement for travel-related costs incurred in association with their participation in the study, the following travel options will be available for site coordinators to select (see WCM Finance travel reimbursement policy on intranet for guidance):

Drive – this payment option automatically calculates the reimbursable roundtrip amount based on distance from a subject’s registered address and a site’s address and a set mileage rate. The default settings of: 1) roundtrip, 2) subject’s registered address, and 3) site’s address, can all be adjusted per request if needed

Flight – this payment option allows a free-form amount to be entered along with start location, end location and a required comment / note explaining the reason

Hotel – this payment option allows a free-form amount to be entered along with a required comment / note explaining the reason

Meal – this payment option allows a free-form amount to be entered along with a required comment / note explaining the reason

Parking & Transportation – this payment option allows a free-form amount to be entered along with a required comment

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Other – this payment option allows a free-form amount to be entered along with a required comment / note explaining the reason

All types of reimbursement, including travel and medicine co-pays require receipts to be uploaded to the ClinCard system for budget verification. Please keep the original receipts as the ClinCard system only temporarily stores them quarterly for project review.

### 4.0 PROCEDURES

4.1 The Greenphire account with WCM/NYP is maintained by the Joint Clinical Trials Office (JCTO).

4.1.1 Study financial reconciliation to be two times per month. If a sponsor requires a different timeline, please contact [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu) to discuss.

4.2 The JCTO is responsible for maintaining and distributing the ClinCards and overseeing financial accounting related to studies included in the system.

4.2.1 Department to e-mail completed request [form](#) to JCTO at [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu) requesting to implement ClinCard on their research project; *open the form from the website in Adobe and sign electronically*

4.2.1.1 JCTO to determine feasibility of implementing and roles and responsibilities on each research project (ie admin, site coordinator, etc.); license requirement; add individual to system

4.2.1.1.1 JCTO to respond with approval / denial / or alternative; if approved instructions on submitting ICF for IRB approval and link to training materials will be forwarded to requester

4.2.1.1.2 Once approved for access, you will receive an e-mail from Greenphire with instructions re: user name and password (the ClinCard system does not use your CWID and password) and must be actioned within 48 hours of receipt

4.2.1.2 Research team admin to build study in ClinCard system

4.2.1.2.1 Study naming convention – PI last name, Sponsor, IRB protocol number

4.2.1.2.2 Include fund or SAP number in Study ID box when building study

4.2.1.2.3 Include social security number (SSN) as optional on drop down menu; allows for including SSN as needed

4.2.1.2.3.1 For foreign nationals participating as subjects in clinical research, please include their federal ID number. If not available, include overseas address.

4.2.1.2.3.2 If you plan to compensate a subject \$600 or more in a calendar year, include the social security number at the time of assigning the card.

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- 4.2.1.2.4 Assign Maria Enamorado, JCTO Finance ([mae2033@med.cornell.edu](mailto:mae2033@med.cornell.edu)) as an approver when building study(s)  
*\*Of note: System automatically logs user out after 15 minutes of no activity; system does not auto save; to save work while building study press submit and re-access via "edit study"*
- 4.2.1.3 ClinCard fees: pharma/biotech/device – \$4 per card and \$1 per load\* fee (based on study visits) for all other projects please contact [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu)
  - 4.2.1.3.1 Card and load fees will be charged to industry budgets and as allowable to federal and foundation budgets; if not allowable on federal and foundation budgets, fees will be charged to department / division budgets
    - 4.2.1.3.1.1 The \$4 card fee will be charged the first time the card is used, along with \$1 for each individual load / transaction fee.
  - 4.2.1.3.2 Departments / divisions (research teams) are responsible for invoicing study sponsor for all ClinCard related card and load fees
  - 4.2.1.3.3 JCTO to process JV using fund number provided in ClinCard Request Form
    - 4.2.1.3.3.1 Study financial contact to receive twice monthly notifications from JCTO re: ClinCard transactions and total JV amount to be processed
  - 4.2.1.3.4 Unused cards can be redistributed to another study within the same department / division if the cost of the card fee is billed to department / division, rather than study budget
    - 4.2.1.3.4.1 Additional cards for a study can be ordered by completing a new request form and submitting to [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu). Include in the body of the e-mail that you are ordering more cards for an existing study.
  - 4.2.1.3.5 Cards will expire on the date posted on the card in the envelope window; study or department is responsible for card replacement cost upon expiration  
*\*Of Note: Due to not accepting card returns, only order the number cards necessary for study start-up. You can order additional cards as needed.*
- 4.2.1.4 Reimbursement receipts – research team to scan receipts and upload to ClinCard system; each form of travel should be uploaded separately; maximum size limit per document is approximately 7mb (recommended to re-size and make smaller)

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- 4.2.1.4.1 Unscheduled visit payment – brief rationale for visit should be included in notes box (holds 300 characters maximum including spaces)
- 4.2.1.4.2 Standard policies for document retention and storage apply; receipts (hard copy or electronic) to be stored by department/division as highlighted under the links listed by contract type: [NIH](#) close of grant plus three (3) years and [NYS](#) end of grant plus six (6) years; all others according to [IRS](#) policy seven (7) years for audit purposes unless otherwise specified in the contract.
- 4.2.1.5 Closing out a study – a study should only be closed in the system once all subject final visits are complete; once a study is closed no subjects can be registered to the study and no payments can be made; department/division to e-mail [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu) to close out. Include PI Last Name, Sponsor Name, IRB Protocol #.
- 4.2.1.6 Removing user access – in the case where a user moves off a study or leaves the institution, study coordinator or admin sends an e-mail to [clincard@med.cornell.edu](mailto:clincard@med.cornell.edu) with ClinCard user name and WCM e-mail; JCTO to send e-mail with request to Greenphire; Greenphire adjusts in the system back-end in order to maintain audit trail; new user role to be assigned as applicable
- 4.2.1.7 JCTO to oversee processing of 1099 tax forms with WCM accounting department as appropriate for subject compensation over \$600 in a calendar year  
*Of note: If subject compensation on your study is going to be \$600 or more per subject, per calendar year, please include a social security number in the ClinCard system*

ClinCard companion user guides located in the JCTO [Researcher's Toolbox](#) under Training and Education Tools and Templates

[ClinCard Admin Reference Guide](#)

[ClinCard Site Coordinator Reference Guide](#)

[ClinCard Quick Reference Guide](#)

[ClinCard Reference Receipt Upload](#)

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### 4.3 USER ROLES

The following includes an overview of what each user role can see / access in the system.

<b>Stored Information within ClinCard</b>	<b>Site Coordinator</b>	<b>Approver</b>	<b>Report Viewer</b>	<b>Admin</b>	<b>Super User</b>
Appointment Date & Time	X		x		x
Approver Comment/Note	X	x	x		x
Milestone/Visit Name	X	x	x	x	x
Payment Amount	X	x	x	x	x
Payment Comment/Note	X	x	x		x
Payment Date	X	x	x		x
Site #			x		x
Site Coordinator Name	X	x	x	x	x
Site Name (Weill Cornell Medical College)	X		x	x	x
Study Name (PI last name, Sponsor name, IRB #)	X	x	x	x	x
Last 4 Digits of Card #	X		x		x
Last 4 Digits of SSN (required to file 1099s)	X				x
Subject Study Status (Screening, Enrolled, etc.)	X				x
Initials	X				x
Subject Address	X				x
Subject DOB	X				x
Subject Email	X				x
Subject ID	X	x	x	x	x
Subject Name	X				x
Subject Phone	X				x