



MONTEFIORE MEDICAL CENTER

Office of Clinical Trials Greenphire Clincard Policy and Procedures

SUBJECT:	RESEARCH SUBJECT REIMBURSEMENT GREENPHIRE CLINCARD SERVICE
OWNER:	OFFICE OF CLINICAL TRIALS
EFFECTIVE DATE:	07/01/2021

Policy:

Principal Investigators (PI) conducting clinical trial research at Montefiore Medical Center (MMC) are able to process subject reimbursements on the day of a subject's visit. As per institutional policy JF07.1, the Greenphire Clincard replaces the previous cashier process for research reimbursement.

Purpose/Scope:

The purpose of this policy is to define how Principal Investigators and their research staff should execute the subject reimbursement process at Montefiore.

Definition

Compensation/Reimbursement is the payment human subjects, involved in a study, receive for their time and effort or for out-of-pocket expenses incurred as a result of participating in the study, such as study-related travel, lodging, or meals.

Policy/Procedures:

- Complete and submit the **Greenphire Application** along with the study budget, contract, protocol, and IRB approved Informed Consent Form (ICF).
- Subjects should be paid in accordance to what is listed in the ICF, any additional payments require approved documentation
- Users receive system credentials upon initial training.

Investigational Review Board (IRB)

Please refer to link

IRS Tax Requirements

The Institution is obligated to report to the IRS all non-employees (U.S. Citizens or Resident Aliens) who receive income greater than the annual threshold of \$600. To this end, studies providing over \$600 per year in reimbursement require that the *IRS W-9* form be collected from human subjects.

To determine if the study requires a W-9 to be collected, refer to the study's informed consent and approved schedule of payments. Principal Investigator or their delegate is responsible for securing a signed IRS W-9 from the subject during the first study visit.

Upon collecting the IRS W-9 form from the subject, a scanned version of the form must be emailed to the Office of Clinical Trials. The IRS 1099 form obtained by the Office of Clinical Trials from Greenphire, reports the various types of income received throughout the year. The W-9 forms and 1099 form will be submitted to Account Payable, who will track cumulative payments to individuals based on Social Security Number (SSN).

Confidential Subject Information

Many investigators feel it is unnecessary or a breach of the research subject's privacy to collect and distribute Social Security Numbers (SSNs); however, we are obligated by law to collect and report human subjects' income without breaching their privacy. The IRS receives the recipient's name, identification number (SSN), street address and total income from the Trustees of Montefiore Medical Center. The information provided to the IRS does not identify the recipient as a study participant or the purpose of the payment.

Since the W-9 contains the individual's Social Security Number (SSN) and other potentially sensitive data, it should be protected. The best way to protect this sensitive data is to maintain the original document in a locked and secure place and/or proceed with destruction per institutional and departmental policy after confirmed submission/receipt from the Office of Clinical Trials.

Non-Resident Alien

If a non-resident alien does not have a Social Security Number (SSN) he/she is only entitled to receive under \$600 within a calendar year. Contact the Office of Clinical Trials (OCT@montefiore.org) for further information regarding how to enter non-resident alien's information into the Greenphire Clincard system.

General Greenphire Clincard Card Rules

- Greenphire Clincards are issued to the study team based on the expected number of subjects to be enrolled into the trial.
- Greenphire Clincards are study specific and may not be utilized for other trials or purposes.
- Greenphire Clincards are to be kept in a locked and secured place.
- **One card** is to be issued per subject for the duration of the study or upon card expiration.
- Greenphire Clincard envelopes should solely be opened by the study participant.
- Greenphire Clincards mailed to subjects should be sent via certified mail, at the department's expense, to ensure receipt by the study patient.

Card Expiration

Greenphire Clincards have a 3 year expiration date. Expired cards should be reported to the Office of Clinical Trials Greenphire Clincard administrator's attention so replacements may be issued.

Lost/Stolen Cards

The Office of Clinical Trials will not replace lost or stolen Greenphire Clincards. Subjects must contact Greenphire directly at 1-866-952-3795. Greenphire will replace the card for a nominal fee and transfer the remaining funds onto the new card. The replacement card will be mailed to the subjects' home address, provided the correct address was entered into the Greenphire Clincard system during subject registration.

Disbursement of Funds

Payment requests will be automatically approved, and monies will be placed into subjects Greenphire Clincard within 2 minutes of the payment request, weekends included.

If a payment error is made, payment reversal is problematic and not always achievable. The study team and its Greenphire Clincard data entry person (the person entering payments) are accountable and responsible for the correctness of payments remitted to subjects.

Clinical Trials Management System (CTMS)

Once a payment request is entered into the Greenphire Clincard system study teams must ensure to enter visit information in appropriate CTMS.

Unused Cards/Study Closure/Returning Cards

All unused cards must be returned to the Office of Clinical Trials, Greenphire Clincard Administrator.

Cost /Finances

The Office of Clinical Trials covers the cost of utilizing the system, loading money onto the cards and the cards themselves. However, on a monthly basis the Principal Investigators fund will be charged for the amount of money disbursed to subjects.

Who to Contact?

When experiencing issues related to Greenphire Clincard, the users should immediately contact the Greenphire Clincard Administrator, **Carmen Rodriguez** (carmrod@montefiore.org) at the Office Clinical Trials. Such issues include but are not limited to: incorrect visit selection, voiding a visit entry, wrongly entered visit dates, verifying payments or any functional issues noticed within the system. In the event that multiple users are experiencing similar issues this is the only way to be made aware of them, and corrected.