Participant Remuneration
Standard Operating Procedures
Purpose
To establish standard operating procedures for the use of standard tools to disburse and monitor participant remuneration.

Overview
All studies compensating or reimbursing patients for participation in a clinical research studies will follow standard guidelines and processes. For studies that reimburse participants, the BoA card program will be utilized; while, studies that compensate participants will follow the BoA card program or apply for a waiver.

Definitions
Bank of America (BoA) Prepaid Administration Tool (PAT): Browser based service that allows for ordering and disbursing of prepaid Bank of America gift cards.

Treasury Services: The department that provides the safekeeping, management, recording and timely reporting of the institution's cash and investments, debt position, provide financial oversight of disbursements

Clinical Research Finance: The department that oversees the operational compliance related to the financial aspects of clinical research

Remuneration: Any payment received for participation in a research study. For a given study, the sum of reimbursement, compensation and other payments is equal to the remuneration.

Reimbursement: Cash or cash equivalents given to study participants to defray the actual out-of-pocket expenses of participation in a research study such as transportation, parking or hotel stays.

Compensation: Cash or cash equivalents given to study participants for time spent, inconvenience. Amounts exceeding a specific threshold in a single calendar year are reportable to the IRS as income.

Cash or Cash Equivalent: Cash, check, pre-paid cards, and vouchers, e.g. parking, transportation or meal.

Non-monetary items: items of value that could include t-shirts, mugs, tote bags, exercise equipment, etc.
BoA Card Fees

The cost of the Bank of America Cards should be negotiated into your sponsor budget. If the sponsor is unwilling to cover the cost associated with the BoA program then the department will assume responsibility.

The fees associated with each card are:

<table>
<thead>
<tr>
<th>Service</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Load</td>
<td>$3.50</td>
</tr>
<tr>
<td>Reload</td>
<td>$.50</td>
</tr>
<tr>
<td>Lost/Stolen*</td>
<td>$5.00</td>
</tr>
</tbody>
</table>

*Patient is responsible for any lost/stolen card after receipt of the card has been confirmed.

STOP

The setup of your account for participant remuneration must be completed prior to study activation. Failure to do so will result in a delay in activation.

Account Setup for Bank of America Card Program

The research study must have been approved by the Institutional Review Board (IRB) with remuneration guidelines specified. To gain access to the BoA program funds allocated for remuneration will be transferred from the study chart field string to the BoA account.

Each participating department will identify the study lead staff member (ex: program manager, etc.), a requestor for the study funds (ex. admin assistant), a receiver for the cards (– if received in office), and a reconciler (please ensure that institutional requirements for segregation of duties are considered).

1. Complete the BoA Setup Request Form located on the Clinical Research Finance intranet site here.
2. The Completed form should be sent to CRF-Participant Remuneration.
3. CRF will coordinate with Treasury Services to get each study account set up in the BoA PAT Tool.
4. After accounts have been set up in PAT; Treasury Services will grant access for all staff listed on the enrollment form. Users will receive a username and password from Treasury Services.
5. The department should check with staff to see if all employees on the Funding Request form have been emailed user ID information to access the BoA PAT system. If staff have not received the email, follow-up with Treasury/CRF to set up users in the system and send them their log-in credentials.
6. All users should familiarize themselves with these Standard Operating Procedures for Participant Remuneration and the Bank of America PAT User Manual.

10/20/2016
Exempt Studies
Clinical research studies involving compensation to participants may apply for an exemption from the BoA card program using the Waiver Exemption form. Waiver types include:

- Studies that are 100 % Federally Funded
- Studies with compensation below $20.00/ participant
- Studies with funding below $50,000 / study
- Studies with maximum enrollment is less than 20 participants
- Studies funded through the CPRIT program

Other exemptions may be granted based on information provided on the waiver form.

Workflow
Treasury Services will hold training sessions twice a month. Registration for these sessions can be found in the Education Center by searching for **Participant Remuneration-PAT Training**. For additional guidance, the PAT user guide can be found in Appendix D.

**Working in the Prepaid Administration Tool (PAT)**

The ordering and administration of the reloadable cards is done via the BoA Prepaid Administration Tool. The PAT User Guide will walk you thru step-by-step instructions. You may access the user guide [here](#).

**Documenting Participant Remuneration**

In all cases, either a compensation or reimbursement form should be completed before the issuance of a card. (See definitions for compensation and reimbursement above). Participants receiving compensation in excess of $600 should be made aware that MD Anderson will report to those earnings to the IRS. Clinical Research Finance will work with Treasury Services and Accounts Payable for accurate reporting to the IRS.

**Monthly Operations**

**Department Reconciliation**

Each study account should be reconciled on a monthly basis. Treasury Services will send a monthly account reconciliation report (see below).

![Behavioral Science - Account Reconciliation-YTD as of July 31 2016.xlsx (25 KB)](#)

This account reconciliation shows the money spent year to date. The PI/designee should review to ensure that the balance in the account is correct. Additionally, this report should be used to determine if additional funding should be loaded to the account. It is the department’s responsibility to develop procedures for reconciliation. The following should be taken into consideration:

- Remuneration should be reconciled by a staff member other than the card issuer/reloader on a monthly basis.
- At a minimum, the reconciliation process should compare the source Compensation Form with Load Activity Report to confirm the transaction was processed as documented.
- Staff members performing reconciliation will then complete the Reconciliation portion of the Compensation Form by entering their name as **Supervisor/Reconciler** and entering the **date** of the reconciliation.
Appendices

Appendix A: PAT Access

Access Types

- **PPDA (Prepaid all)** – Access to order, load and issue card, and view reports. [DA/reconciler/project manager as department sees appropriate]
- **PPIC (Prepaid Inventory Control)** – Order prepaid instant issue cards only
- **PPDL (Prepaid Loader)** – Only has access to load funds on cards
- **PPDO (Prepaid Order)** – Access to enter participants’ information (personalized mail order cards) and issue cards.
- **PPV** – Only access to run and view reports and view card profiles.

Appendix B: Instant Issue versus Personalized Cards

<table>
<thead>
<tr>
<th>Feature</th>
<th>Personalized (Mail Order)</th>
<th>Prepaid Inventory (Instant Issue)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order cards using</td>
<td>Mail Order Tab or Bulk Upload Tab</td>
<td>[Need to add detail]</td>
</tr>
<tr>
<td>Issue cards and load funds using</td>
<td>Mail Order Tab or Bulk Upload Tab</td>
<td>Instant Issue Tab or Bulk Upload Tab</td>
</tr>
<tr>
<td>Bank of America Sends cards to</td>
<td>The Individual OR the location</td>
<td>The location ONLY</td>
</tr>
<tr>
<td>Cards can be reloaded</td>
<td>Unlimited times</td>
<td>3 times</td>
</tr>
</tbody>
</table>

Appendix C: Forms

The PI/designee will be responsible for the accurate tracking of all activity related to the disbursement of participant remuneration. Each patient is required to complete the reimbursement or compensation request form. These forms assist both the patient and study team with expectations for remuneration. The study team will keep these forms for auditing and close out purposes.

**Bank of America Funding Request**

Complete the Funding Request form by filling in the following items:

- Date
- Requestor
- Department Name
- Principal Investigator
- Total Amount to be Funded – this represents the total amount you would like to be charged to your Chartfield String. This amount can be increased at any time to cover additional requirements.
- Chartfield String – account of the project
• Program(Protocol # and Principal Investigator
• Maximum Initial Load per Card
• Maximum Reload per Card
• Maximum Balance per Card
• Estimated Number of Cards per Year
• Estimated Dollar Amount per Fiscal Year-Be sure to allow yourself room enough to accommodate the requirements of the trial.

Compensation Form
• Individual departments or PIs will determine who shall be responsible for completing the Compensation Form. Different staff may be responsible for filling out different sections of the form.

Study Demographics Section
• Appropriate staff member shall fill out the study demographics form.
• Date submitted shall refer to the date of the relevant action for the card (issuance/load/etc.).
• Protocol Number should be matched to the Location in the BoA system.
• PeopleSoft Chartfield should match that given in the funding request form
• PI/Project Name should match that in the BoA System
• Study Demographics Section

Participant Information
• Appropriate staff member will fill out sponsor accession number (if applicable), and the Study ID/CORe Accession No. (If applicable). [Some studies specifying no direct link to identifiers may opt to leave off the Study ID/CORe Accession No.]
• Study staff or participant may fill out the participant information depending on procedures for the individual study.
• This includes the participant name, mailing address, city, state, zip code, and phone number. The email address field is optional, but recommended.
• Note on the form if number is a cellular number or a home phone number, as this will need to be entered into the PAT website.

Basis for Compensation
• A designated staff member will fill out the Basis for Compensation section.
• Visit date is the date that the study participant completed the study procedure that corresponds to the compensation. This date should match source documentation for that visit.
• **Visit Number** may vary by protocol and should be defined by the study staff (e.g. baseline = visit 1, 3 month follow up = visit 2, etc.). Please note that visit may refer to a study procedure versus an actual clinic visit depending on the study.

• Check the appropriate box for **visit type** (in person, phone, mail, or email/web).

• Check the appropriate box(s) for **expense type** (study compensation, other, parking, public transportation/taxi).

• Fill in the amount of compensation.

• Fill in the name of the study staff member who conducted the study visit under “**Conducted by**”

• The **comments** box should be filled in if the expense was listed as “other” to specify the type of expense.

• Study staff should confirm that the participant information is up to date.

• The participant shall sign to confirm receipt of the card and date if appropriate. [Not all protocols require participant to sign]. *If card was dispensed via mail, note that in the participant signature field. Make sure to include appropriate documentation of the mailing per the protocol in the other regulatory documents.*

• The appropriate staff member shall sign and date. This should be someone who has verified that source documentation supports the compensation. This will most often be the person who conducted the study visit, but can be other designated staff.

• **Optional procedure**: Clinic staff will have participant activate the card in clinic to troubleshoot with participant if any issues arrive during this process and to avoid problems later with participants going home with non-functional cards. Prior to activation, staff should explain how the card works and discuss the fee structure with the participant. In particular, the participant should be informed about the cost to replace the card if it is lost/stolen and what they need to do in the event that this occurs. Some studies may wish to have participants sign an acknowledgement form detailing this information to ensure understanding. Remind participant that they are responsible for the card for the duration of the study.

*Disbursement Authorization*

• Card can be issued/reloaded by the appropriate staff member once Compensation Form is in hand and all signatures have been obtained.

• After issuing/reloading, the person who issued/reloaded the card will fill out the Disbursement Authorization portion of the Compensation Form.

• **Activation date** is actually the date that the card was issued or reloaded. Study staff may not know the actual activation date since the participant may activate on their own.

• **Entered by** should be the name of the person who issued/reloaded the card.
• **4-Digit card number** should be the last 4 digits of the actual card. In the case of mail order cards, the study staff will need to run a report to get the actual card number.

• **Confirmation #** should be the confirmation number for bulk uploads (if applicable).

• The form should be retained as documentation.

• *Note: cards should not be issued in advance of a participant’s visit in case they do not come to the clinic or are not eligible to receive payment. Bank of America recommends card status be updated to “Suspend” if issued to the wrong individual.

• It may be advisable to write the participant’s ID, initials or both on the back of the card and/or on the card envelope prior to dispensing the card to the participant.

• After issuing a card, departments may wish to save the confirmation page as a PDF for future reference.

• **Optional procedure:** have a designated staff member download the Load Activity Report from the PAT website at the end of each day to ensure that all payments were correctly processed under the correct protocol. If there are any errors in payment processed, address immediately. Save a copy of the daily report as documentation of the day’s transactions.

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**Reimbursement Form**

• Patient should complete as much information as they can on reimbursement/compensation form prior to meeting with the department. Study staff will complete information such as protocol number, sponsor accession number, study ID/Core accession number. It is critical that a phone number/cell number is recorded as this will be the password on the Bank of America Prepaid card that will allow the patient to access the funds.

• Insure patient has proper support for each item listed as required by the sponsor/contract. All receipts should be taped to an 8 x 11 sheet of paper and should be easy to read.

• Participant will sign the form in Participant Acknowledgement area. Study team member will then co-sign attesting that we have received the form from the patient with all necessary documentation.

• Once form is complete and all signatures obtained, forward form to the appropriate departmental person responsible for collection and follow departmental SOP in processing for payment.

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**Appendix D: Bank of America PAT User Guide**

**Prepaid Administration Tool User Guide**