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"Happy Trials to You"

Disbursing Cash and Cash-Equivalent Incentives for Study Participants By Piotr T. Dybas and David W. Allen

Participant incentives are transfers of value to study participants that encourage their participation in a clinical study and provide compensation for the time, inconvenience and discomfort that participation might cause. Most such incentives take the form of cash or a cash equivalent, and are commonly called "stipends." This article will discuss the practical aspects of different types of cash and cash-equivalent incentives. It will not discuss reimbursement for participant expenses, such as parking, or other motivations, such as medical treatment or altruism.

There are four types of cash and cash-equivalent incentives:

- **Cash** is very flexible and can be available almost instantly for immediate gratification. However, it requires stringent security measures.
- **Checks** are very flexible, a close equivalent to cash, and require modest security measures. However, they create an administrative burden on both the site and the study participant.
- **Gift cards** (VISA, American Express, MasterCard) are very similar to cash. However, they are less flexible than cash and, if not personalized, require security measures comparable to those for cash. Some vendors allow two lines of custom embossing, allowing the purchaser to add a name and message or unique identifier.
- **Retail Gift cards** (Target, Walmart) are similar to cash at the issuing retailer's stores.^{1,2} There is no purchase fee and the cards can offer promotions like free shipping. A wide variety of designs are available.
- **Incentive management systems** provide substantial capabilities for managing gift cards and tracking their use.

Table 1. Patient Incentives Process and Issues

| Туре | Process | Issues |
|--------|---|--|
| Cash | Hold cash in a secure location. Maintain a disbursement log. Require recipient to sign a receipt that includes his or her name, date, amount, study name, and name of person disbursing cash. Periodically count cash and reconcile to disbursement log. | Access to cash might be cumbersome. Cash must be transferred person to person, i.e., at a study visit. Cash, in and of itself, does not provide any documentation of its transfer in case there is a dispute about the payment. Cash can be paid in the wrong amount, lost, stolen or just disappear. Cash can attract criminals, who might cause injury or property damage. The presence of significant amounts of cash should be reviewed by the site's insurer. |
| Checks | Generate checks prior to or after study visits. | It is time consuming to request and generate checks. |

| | Hold unissued checks in a secure location. Maintain a disbursement log. Transfer checks in person or by mail. If giving check in person, ask recipient to sign a receipt that includes his or her name, date, amount, study name, and name of person giving the check. Review bank account statements for checks that have | If transferred at visit, study coordinator must remember to request a check and give it to the participant. Checks generated prior to a visit may have to be stored, mailed or destroyed. Envelopes and stamps incur a small additional cost. If a participant does not remember or admit to receiving a check, it takes time to resolve the issue. Lost checks incur stop-payment fees and incur an additional administrative |
|---|---|--|
| Gift Cards (VISA American Express/Maste rCard/Retail Outlet) | been cashed. Hold cards in a secure location. Maintain two issuance logs using tracking numbers on cards, one for issuance to study coordinators and one for issuance to participants. Issue cards in person, requiring recipient to sign a receipt that includes his or her name, date, amount, study name, and name of person disbursing check. Periodically inventory cards and reconcile to issuance logs. The IRS treats gift cards as income for the recipient, so reporting on Form 1099-MISC is required, as with cash and checks. | Cards for a specific retail outlet might not provide value to all participants. However, more than one type of card could be used, subject to minimum order quantities and logistical considerations. There might be additional costs, e.g., for shipping the cards to the site. Cards might be limited to certain values that do not fit a study's requirements. An unusable balance might be left on an issued card. Some cards can be recharged or, if lost, cancelled and reissued. Unused cards usually cannot be refunded. Some states allow card issuers to charge fees to gift cards if they are not used in a certain amount of time. It might be necessary to manage multiple types of cards for different studies and types of participants. |
| Non-cash- equivalents | Toys, stuffed animals, books, electronic devices, travel vouchers, T-shirts, and like items can provide significant value to participants, without the complications of a monetary payment. The IRS classifies non-cash incentives as taxable income, unless exempt, which is reportable on form 1099-MISC if the total amount exceeds \$600 in a calendar year. | Such items might not provide value to all participants. However, more than one type could be used, subject to minimum order quantities and logistical considerations. There might be additional costs, e.g., for shipping the items to the site. Storage might be an issue. Unused items usually cannot be returned for a refund. |

Commercial incentive management systems provide a better, more reliable experience for both sites and study participants. Some companies offer cards that can be used at ATMs or wherever major credit cards are accepted. (Gift cards might not allow their use at ATMs or might require the user to create a PIN.) The risk of the credit card disbursement and tracking is taken by the commercial provider that provides the service for the study. The cost of an incentive management system is offset by the reduced administrative burden, especially with large-scale use.

Any incentive management system, whether home-grown or licensed from a software provider, should include the following elements:

- **Appeal to Study Participants.** Incentives must provide value to study participants, with a minimum of hassle.
- **Reasonable Administrative Burden.** Incentives should not be overly complex and time-consuming to administer, e.g., when dealing with a lost check or gift card.
- **Physical Security.** Cash, unissued checks, and gift cards should be kept in a safe or other secure place, with controlled access. Lockboxes are less expensive and can be more convenient than a safe, but they are less secure due to their portability, construction and locking mechanism. A locked desk drawer provides minimal security. Since personnel can change, a programmable code is preferred. On the other hand, it should not be too time-consuming to open the safe so, for convenience, the bulk of the incentives can be kept in a very secure place and the incentives for the day in a less secure place.
- **Data Security.** Incentive data includes Social Security numbers for IRS form 1099-MISC filings, so the data should be secured by encryption and controlled access.
- **Tracking and Reporting.** Cash, checks and gift cards must be tracked, reported and reconciled. The incentives account must remain open until all transfers have been completed and reconciled.
- **Standard Operating Procedures.** There should be written policies, procedures and forms.

Conclusion

Patient incentives are worthwhile in many clinical studies. Different forms of incentives provide different experiences to study participants and impose different levels of administrative burden. Thoughtful consideration of these characteristics will provide the best solution for a give research site and study.

References

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