

Guidance: Subject Payments

Incentive payments can be made to individuals who participate in human research studies in acknowledgement of their time and effort. Incentive payments can be checks, gift cards, or in-kind incentives (gifts, fee-waivers, etc). Subject payment raises ethical issues around voluntary participation and the individual's need to make informed choices about participation based on the risks and benefits of the research, not on financial incentives. The Food and Drug Administration (FDA) cautions against payments that are "coercive or present undue influence," and the National Institute for Health (NIH) similarly warns about payments that cause "undue inducement." However, the federal regulations set no strict limits on financial incentives, leaving investigators and local IRBs to decide how much payment is too much or not enough. These payments may represent taxable income to the subject. Wright State has withholding and reporting responsibilities to the Internal Revenue Service (IRS) in connection with these payments. This guidance is intended to govern all payments to research participants by providing guidance to investigators regarding payment types, tax reporting requirements, and the process for submitting payments to accounts payable, if required.

Principal investigators (PIs) and other faculty/staff members who are conducting sponsor funded research, internally funded research, or investigator-funded research are responsible for:

- informing all subjects that any payment received for participation, regardless of amount, is taxable income
- ensuring that subjects are eligible to receive payments (in accordance with U.S. Tax and Immigration laws)
- ensuring that the payment process is appropriate
- Completing payment receipts and a distribution log for payments

NOTE: Payments made as part of an investigator funded research project do not need to submit documentation to Wright State accounts payable department. Investigators are expected to comply with all other tracking requirements and IRS regulations reporting requirements.

Following these general cautions and based on its own experience, the IRB has developed recommendations about subject payment.

- The proposed method and timing of disbursement should not be coercive or present undue influence. There are no hard and fast rules about how much subjects should or should not be paid. Subjects should be paid enough to make up for their time and trouble, but not so much that their decision to volunteer or continue in a study is influenced by the amount being offered. Subjects should not see research participation as a way to make a living or regularly supplement their income. Large payments can suggest this possibility and can be coercive.
- Payment should not be contingent upon completion of the entire study. Holding payment until the subject has completed every procedure in a long, multi-week, multi-visit study is inappropriate. For studies with more than two or three visits, payment should be prorated, that is, based on the amount of time subjects have spent participating so far.

- Payment to participants who withdraw from the study should be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn, unless it creates inconvenience or a coercive practice.
- Payment to research participants for participation in studies should not be included as a benefit in the analysis of risks and benefits.
- Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn. This bonus should not be more than 30% of the total available payment.
- No matter how payment is calculated (hourly, per procedure, or some combination of both), all information concerning payment, including the amount and schedule of payments should be set forth in the informed consent document.
- Compensation for participation in a trial offered by the sponsor should not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- Payments to the organization or research staff designed to accelerate recruitment and are tied to the rate or timing of enrollment is prohibited.
- Small refreshments or snacks provided to participants during a study are not considered incentives.
- When conducting research with a vulnerable population or in international settings, you should take into consideration whether small gifts or incentives have greater impact due to a particular population's culture or economic situation, and clarify this context in the protocol.

Special rules that apply to drawings/lotteries/raffles

There are various federal guidelines including IRS rules, State of Ohio laws [ORC2915.01(D)], and other statutes that apply to raffles and lotteries. When proposing to offer a research-related drawing as a form of compensation, researchers should use the following guidelines to minimize the likelihood of triggering legal issues.

- Researchers should use the term “drawing” rather than “lottery” or “raffle,” since the latter terms imply purchase of tickets by participants.
- To further avoid the possibility that a drawing would be perceived as a lottery, the protocol should describe procedures for ensuring ***that all individuals who are contacted concerning the research will be allowed to enter the drawing***. This would encompass individuals who are invited to participate but decline, prospective subjects who are ineligible, subjects who enroll but later withdraw/are withdrawn by the researchers, and/or subjects that do not complete every question.
- The drawing must be conducted in a manner that does not compromise participant anonymity or confidentiality that is protected by other protocol methodologies.
- The protocol and consent document(s) should also include the following information:
 - Description of the prizes, including estimated value, and the total number of prizes to be awarded. Both the amounts and number of prizes must not be coercive or exert an undue influence on participants, and the disparity between participants should be considered (i.e., it is preferable to have several lower value prizes rather than one higher prize because the inequality between participants is reduced).
 - The odds of winning a prize, if known, or explanatory language similar to this: “For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do

not know how many people will participate in this study related drawing, we cannot predict what will be the odds of winning a prize.”

- The approximate timing of the drawing (e.g., month/year).
- How prize winners will be notified.
- The researcher, any co-researchers or research assistants named in the protocol, immediate family members (spouse, parents, siblings, and children) of such persons, and any other persons with a direct interest in the research study must be excluded from participation in the drawing; and
- The researcher must maintain records regarding the drawing along with other research-related documents.

Payments to Nonresident Aliens

Special processing requirements apply to payments to nonresident aliens. Investigators and the university must comply with regulations of both the IRS and the Department of Homeland Security. The rules regarding payments to nonresident aliens are complex and the penalties for violations are harsh and can include deportation from the United States.

For all payments, a potential subject’s citizenship status must be reviewed before the subject is enrolled in the study. The review is intended to ensure that the person’s visa category allows them to receive income from the university. Payments to nonresident aliens must be processed through Accounts Payable, depending on the source of funds (e.g., sponsored projects, internal funding). For payments processed through Accounts Payable, each research subject is required to complete a Compliance Form (substitute W-9).

Payments to University Employees

University employees may receive research subject payments like any other subject, provided that their participation is entirely voluntary, is outside of their work schedule, and is clearly unrelated to their employment duties. Payments should be processed in accordance with the Accounting Giftcard policy.

Reporting Payments to the Controller’s Office for Taxes

All payments for participation in research must be reported to the Office of the Controller in accordance with the Accounting Gift Card policy.

How to Pay Research Subjects: Accounts Payable Procedures

Below is a summary of payment methods. All payments must be logged on the Distribution Log (Gift Card Accounting Policy and Procedures Appendix A). Distribution logs will be securely submitted electronically to Accounts Payable and the Payroll Department by December 15th to be consolidated and reviewed for annual tax reporting on IRS Form 1099 or 1042-S.

Bearer Checks

Bearer checks require a PO issued through Wright Buy using Account Code 717305 for IRB Human Subjects and Activity Code GCARD. Internal comments must include **IRB Number and date of IRB approval along with acknowledgement of policy and tracking requirements**. A release email to accounts_payable@wright.edu is also required to print needed Bearer checks.

Gift Cards

Gift cards may be used for single payments, or payments in aggregate, for all research subjects. Although gift cards are somewhat similar to cash or checks in their use, the mechanism by which they are managed is quite different. We strongly discourage the use of physical gift cards. When possible, E-gift cards are preferred and should be purchased in small batches as needed.

Gift Card Purchase – Sponsored Projects & Internal Funds:

Gift cards are obtained through Purchasing. Gift card purchases must be made through the Wright Buy Amazon punchout using a University Pro-card (p-card) for payment. The Office of the Controller or their delegate will approve all gift card purchases. Internal comments must include **IRB number and date of IRB approval along with acknowledgement of policy and tracking requirements**. Account Code 717305 for IRB Human Subjects and Activity Code GCARD are required for these purchases.

It is important to order only the number of cards that will be used because there is no mechanism for returning gift cards that have been purchased but not distributed to subjects. The cost of gift cards remaining at the end of the project will be transferred from the project to the department associated with the project and become department property.

Gift Card Distribution

When a subject has completed participation in the study, the account custodian should issue a gift card, complete a Human Subject Payment Receipt, and have it signed by the subject. The receipts must be maintained securely and confidentially with the project records. A separate receipt is required for each gift card distributed.

Gift Card Reconciliation on a Sponsored Project

While a project is active, the value of undistributed gift cards (gift cards on hand), plus the value of all Human Subject Payment Receipts retained by the project should equal the amount of expense charged to the project for gift cards. When a project is completed, any undistributed gift cards should be given to the appropriate department and the charges for these gift cards should be transferred from the project to the department. A final reconciliation of gift cards on a project should confirm that the value of all Human Subject Payment Receipts retained in the project files is equal to the total expense for gift cards charged to the project.

Mailing or E-Mailing Gift Cards

If gift cards are to be mailed or e-mailed to the human subject in exchange for completing a survey or other purpose that makes collecting subject signatures impractical, the reconciliation is still required.

- there should be two employees in the room at all times while the gift cards are prepared for mailing



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- project personnel must keep a list of recipients with all the demographic information required on the Human Subject Payment Receipt (including the address to which the gift card is being mailed)
- both employees are required to sign the list
- the unit's Fiscal Manager is also required to sign the list

Anonymous Subjects

Contact Accounts Payable for bearer checks if you need to issue payment and the names of the subjects cannot be revealed. Anonymous Bearer checks should be accounted for by submitting a Summary Research Subject Distribution Log as follows:

Attach a list showing research subject reference (i.e., number, first name, and alternate name), date of payment, and amount paid. The check request description must include the following certification:

- "I certify that the (total number) research subject payments referenced on the attached list were payments made for participation in (study name) and that each received the amount indicated."
- Signature of PI or Co-PI
- Signature of witness to payments

For research subject payments an exception to the requirement to record recipient names on the Distribution Log may be granted if the study is of a highly sensitive nature and a Certificate of Confidentiality has been secured from the Department of Health and Human Services. After receiving the Certificate of Confidentiality, Principal Investigators must obtain approval from their Department Chair and from their Fiscal Manager before submitting a formal request to Accounts Payable. If the exception results in any IRS tax liabilities, these amounts will be charged to the PI's department.

Sample Consent Form Wording

The Payment section of the consent form should explain how subjects will be paid (i.e., gift card or bearer check) and how long they will have to wait for payment (i.e., whether they are paid immediately or after a delay of four to six weeks). The most frequent subject complaint heard by the IRB concerns the timing of payment, so it is important to make the payment plan clear from the start.

Example: I understand that the incentive payment I receive for participating in this research study is taxable income and it is my responsibility to report it to the IRS as required by federal law. If you complete the entire study, you will be paid \$400 -- \$50 for each clinic visit and a \$20 bonus for finishing the study. If you withdraw from the study early, you will receive \$50 for each visit you complete. You will be paid by check, and you should receive the check four to six weeks after your last visit. If you receive more than \$600 per year in payments, you may be contacted by research group to obtain your tax reporting information. You will need to provide the investigators with accurate contact information for this purpose. This tax information will be collected at the time of payment distribution for all nonresident aliens.

Social Security Numbers:

Social Security numbers should only be recorded, at the time of distribution, for nonresident alien participants; all amounts are reported via 1042-S. For participants with an aggregate amount of \$600 or more, Accounts Payable will have the responsible party obtain a social security number for 1099 reporting. Explain these reporting requirement(s) in the Payment section of the consent form.

Payment, Reimbursement, or Compensation?

The IRB prefers the term "payment" when discussing money given to a subject to offset time and inconvenience and/or to provide incentive to participate. The IRB reserves the term "compensation" for discussions of Treatment and Compensation for Injury policies. The term "reimbursement" suggests that subjects must provide receipts for particular out of pocket expenses (for instance, parking and transportation), which they often cannot.

Research Incentive Reporting Requirements and Recommendations

Reporting Requirements

- For all studies involving payments to participants, PI must maintain an "Incentive Payment Distribution Log." A sample tracking log can be found on the IRB Forms and Documents page and in the accounting gift card policy.
- Online survey tools such as Amazon's Mechanical Turk (mTurk) do not require the participant's name. However, a unique identifier (such as worker ID) is collected. A report showing worker ID, date of payment, and payment amount may act as a log of study participation.
- For all studies involving payments and/or gift item value amounts to participants over \$25, PI must collect signatures from participants upon receipt of the incentive.
- These records should be kept for 7 years for IRS reporting requirements.
- Logs may be subject to audit but will maintain participant confidentiality

Forms

- Human Subject Payment Receipt
- Gift Card Accounting Policy and Procedures Appendix A "Distribution Log"

References:

Gift Card Accounting Policy and Procedures