Incentives and Reimbursements to Research Participants

I. Introduction

The University recognizes the importance of encouraging individuals to participate in research and values the time, effort, and risk participants contribute to University research efforts.

According to the U.S. Department of Health and Human Services (HHS) and U.S. Food and Drug Administration (FDA), "Paying research subjects in exchange for their participation is a common and, in general, acceptable practice." However, the payment must be ethical. To ensure that the payment is ethical, the University IRBs review the amount of payment, the proposed method, and timing of disbursement of payments to study participants to assure that they do not present undue influence as described in the FDA regulations and the corresponding HHS regulations [45 CFR 46.116, 21 CFR 50.20]

The University permits payments or other non-monetary incentives to compensate participants for their contributions, as long as the following criteria are met:

- Payment arrangements are specifically approved in advance by the relevant IRB;
- Payments or other non-monetary incentives provided to participants in return for their participation are not so significant as to be coercive or unduly influential (e.g., inducing participants to accept unreasonable risks);
- Payments are prorated when appropriate and should not be contingent upon the participant completing the study, to avoid inducing participants to continue in a study when they otherwise would withdraw;
- Arrangements are made by the study team to assure proper accounting of payments made to participants, and required reporting to tax authorities, as required by University policy, with due consideration of privacy concerns.

II. Human Subjects Incentive Program (HSIP)

The University of Michigan Finance Department's Human Subjects Incentive Program (HSIP) Office oversees, processes, and tracks monetary incentive payments for human subject research participation in accordance with SPG 501.07.

HSIP offers multiple methods of payments as monetary payment options. Study team questions related to the HSIP process requirements or payment methods should be directed to the HSIP Office. HSIP processes incentives for IRB-approved studies, including Exempt studies and Not Regulated projects. If a third-party vendor (i.e. Prolific) will be used to distribute the incentives, the study team must first contact HSIP. Note that HSIP will not process incentives distributed by another institution.

Incentive payment for research participation is taxable income. For information that must be collected for participants' incentives distribution please refer to the Human Subjects Incentive Program (HSIP) Office.

If participants are unwilling or unable to provide HSIP required information, participants may continue to participate in research studies, but may not be able to receive payment.

For studies where incentives are being paid to participants outside of the U.S., participants may have different tax reporting obligations. Please contact the Human Subjects Incentive Program (HSIP) Office in order to ensure that these obligations are met and that the study's incentive arrangement is compliant.

For multi-site research, HSIP does not provide payments to non-UM research participants on behalf of other institutions. Participants paid through HSIP must be U-M research participants, consented and enrolled by U-M study teams. This can include participants recruited from other institutions as long as they are considered U-M research participants.

For additional guidance, study teams should contact the Human Subjects Incentive Program (HSIP).

III. Reimbursement and Incentive Payments

Reimbursement and incentive payments have differing requirements.

A. Reimbursement is payment for out-of-pocket expenses that participants incur related to their participation in the research, such as transportation and parking fees. Reimbursement must be documented by receipts and is tracked by Accounts Payable.

In most cases, reimbursement is more acceptable when prorated over the course of study participation. Lump sums, given only upon completion of the entire research project, are generally not acceptable, and investigators will be asked to revise lump-sum payments so as to avoid compromising a participant's decision to withdraw prior to the study end.

B. Incentives are payments made to individuals to compensate them for participation in research projects. The amount paid is subject to Federal income reporting requirements. The HSIP Office is responsible for the distribution, reporting, and monitoring of subject incentives. Typically, incentive payments are disbursed throughout the course of the study and associated with the completion of certain research-related activities, whether done optionally or as a condition of participation, such as imaging assessments, collection of biospecimens, or study visits. Incentive payment amounts are assessed by the IRB to identify any potential undue influence which may compel individuals to participate.

Depending on the research setting or population, incentives may not be monetary in nature and may include cell phone credits or bags of rice/grain (in international settings), or other tokens. Token incentives may include U-M clothing, magnets, and other trinkets. For non-monetary tokens paid to U.S. based participants, if the token is dependent upon participation in the research, language about incentives should be present and can be found in IRBs' informed consent templates (IRBMED & IRB-HSBS). If the tokens provided are not dependent upon participation (e.g. they are given regardless of participation), language about incentives is not needed.

C. Sweepstakes, Research Lottery and Raffles

The following guidance is for drawings that take place in the State of Michigan. Should the drawings take place outside of Michigan, that location's laws would apply. Study teams should contact HSIP in these cases.

1. Sweepstakes

In a sweepstakes, all those invited to participate in the research are eligible to win, whether or not they actually participate in the research. A sweepstakes structure allows for a higher-value prize without requiring a raffle license. Participants (and researchers) will be familiar with sweepstakes from cereal boxes and candy wrappers with a "no purchase necessary to win..." prize offer.

a. Individuals are not required to participate in the research in order to be entered into the drawing
b. Prize may exceed $100
c. The following information must be included in the consent document:
   - Date and location of the prize drawing
   - The odds of winning
   - How winners will be notified
   - Sample consent language:
     You will be entered into a sweepstakes to be conducted on June 15, 2025, for an iPad valued at $499. The drawing will be conducted by the University of Michigan in Ann Arbor, MI. The chance of winning a prize is approximately 1 in 300. The winner will be notified immediately by email and provided with information on where to pick up the prize.

2. Research Lottery/Raffles:

Researchers may also choose to incentivize study subjects by utilizing a lottery payment structure, in which subjects' names are entered in a lottery operated by the study team. If a study's incentive budget is small, a lottery allows one subject, drawn at random from the pool, to receive the full amount of the incentive amount. Michigan law

requires anyone operating a lottery (also known as raffle) to obtain a raffle license from the state; however, an exemption is allowed for qualified organizations to operate lotteries without a raffle license.

As a qualified organization, the University of Michigan is authorized to conduct lotteries without a raffle license, as long as the lotteries meet the following criteria for the statutory exception:

a. Prizes awarded may not exceed $100/day
b. Participants are offered a chance to win a prize in return for their participation in the research study
c. There are no second chance drawings
    - For example, a study team may have $300 to offer as incentives for research participants. They may hold three drawings for $100 on three different days. They may award multiple prizes each day (e.g. four $25 prizes) but the total value cannot exceed $100 on any one day. They must enter three discrete pools of research participants on each day of the drawing (e.g. Participants 1-25 on Day One, Participants 26-50 on Day Two, and Participants 51-75 on Day Three).
d. Sample consent language:
    You will be entered into a drawing for one $100 prize.
    You will be entering into a drawing for one of four $25 Target gift cards.

When conducting a research lottery, the University of Michigan study team is responsible for:

- operating the lottery
- maintaining the pool (or pools) of potential winners
- drawing the winners
- awarding prizes

The State of Michigan Charitable Gaming Division offers guidance on legal requirements for raffles conducted in Michigan. For more information refer to Human Subjects Incentive Program (HSIP).

Should the drawings take place outside of Michigan, that locality's laws would apply. Researchers are responsible for knowing the regulatory requirements for lotteries conducted outside of Michigan.

IV. Referral Fees/Snowball Sampling

For difficult-to-recruit populations, a study team / sponsor may wish to use referral's fees paid to participants. University policy prohibits payment to or receipt by U-M researchers, including staff and students, of these types of payments. Often coupled with snowball sampling, referral fees are paid to participants who share study information with other potential participants. Things to consider:

- The level of engagement necessary to receive the referral's fee should be outlined in the study materials for both the referring individual and potential participants. The fee should not be aligned with activities that reveal whether or not a referred individual has enrolled but could be associated, instead, with an agreement to be screened.
- The study team should not disclose to the referring participant which referred individuals decided to participate.
- Potential participants should be given contact information for the study team and the referred individual should initiate contact with the study team.
- Payment should be of an amount unlikely to provide an incentive for the referring party to pressure the potential participant to engage the study team for screening/possible enrollment.
- To help ensure quality referrals (ie, those who might actually enroll), consider placing limits on the number of referrals for which a participant could be compensated.
- Study teams should utilize HSIP for these payments so any tax consequences are considered. If the payments are made directly by the sponsor, the sponsor should manage tax consequences.

V. Resources

- Standard Practice Guide_501.07
- HRPP OM Part 7. V
- Human Subject Incentives Program

- [45 CFR 46.116, 21 CFR 50.20]
- Traxler-McCauley-Law-Bowman Bingo Act (Act 382 of 1972)
- Michigan Penal Code Act 328 of 1931
- Raffle Guide, Charitable Gaming Division, Michigan Lottery
- IRBMED informed consent document templates
- IRB-HSBC informed consent document templates