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A Note Concerning Paying Research Subjects

Some research projects involving human subjects offer a payment to the research subjects for their participation, a practice that can be traced in the United States to the mid 19th century (e.g., Walter Reed paying volunteers to participate in his yellow fever studies^{*}). Despite the lengthy history of the practice and federal guidelines governing research with human subjects that have been interpreted to permit the practice[†], the ethical propriety of paying research subjects continues to be debated[‡]. The purpose of this *Note* is not to advance this debate, but rather to provide principal investigators (PIs) with detailed guidelines and procedures regarding payments made to individuals participating as subjects in research projects.

Why pay research subjects?

Payments made to research subjects are generally small amounts that provide an incentive for recruitment and participation in the project. These payments are not to be confused with payments made to a participant in a grant-supported conference, meeting, workshop, seminar, symposium, or training program to reimburse the participant for the direct costs associated with participation in these activities[§]. Participant support costs are budgeted differently in the project proposal and accounted for differently if a sponsored program award is made.

Must payment to research subjects be approved?

Federal law (Title 45, Part 46 of the Code of Federal Regulations, *Protection of Human Subjects*) and UMass policy require the prospective review and approval of all research involving human subjects by the university's Institutional Review Board (IRB). The PI is required to prepare and submit a research protocol that provides a description of, and a scientific rationale for, the proposed human subject research activities. The protocol must include, if applicable, the PI's plan to pay the research subjects, including the amount, nature, method, and schedule of payment.

* As reported in Leah E. Hutt's article "Paying research subjects: Historical considerations," *Health Law Review*, 2002, 12(1).

† Dickert, N., et al. "Paying research subjects: An analysis of current policies," *Annals of Internal Medicine*, 2002 (136), 368-373. Grady C, et al., "An analysis of U.S. practices of paying research participants." *Contemporary Clinical Trials*, 2005 (3), 365-75.

‡ See, for example, McNeil, P., "Paying people to participate in research: Why not?," *Bioethics*, 1997 (11), 390-396.

§ Please refer to the *Note Concerning Participant Support Costs* for specific information on the payment of these costs.

The IRB will review the PI's justification for and calculation of the amount to be paid to the research subjects to ensure it is appropriate given the proposed research activities (i.e., complexity, duration) and the population to be recruited (e.g., socioeconomic status, age). In general, payments must be equal and provided to all research subjects. The research subjects should not be led to believe that the payment is either a benefit of participation or a reward for the quality of their performance. In addition, payments should not be so large as to coerce prospective research subjects to consent to participate or to continue to participate in the research project against their better judgment. Payment cannot be proposed as a means to offset research risks – risks that are otherwise unacceptable cannot be made acceptable by offering payments to subjects. The IRB must also review and approve all proposed communication about payment in the informed consent document, as well as advertisements, information sheets, or other documents related to the research project. Only after the IRB has provided its approval in writing to the PI can research subjects be recruited and the research project be initiated in accordance with the approved protocol.

How are payments to research subjects made and accounted for at UMass Boston?

When the proposal is developed for a sponsored program that includes payments to research subjects, the PI must segregate those costs in a separate budget line. All costs associated with such payments will be charged against this budget category if an award is made for the project.

In most cases, payments of small dollar amounts (\$50 per research subject over the course of the research project) are made in cash at the time of the subject's recruitment to and participation in the research project. The PI should request a cash advance using the disbursement voucher form available on the Controller's Office website. The request must state the purpose for which the cash advance is to be used, why standard purchasing procedures are inadequate for that purpose, that the amount and the purpose are necessary and reasonable, and that adequate internal controls and security are in place to safeguard the funds and to prevent misuse.

When making payments of cash to a research subject from the cash advance, the PI must have the research subject sign a receipt of payment, which gives the following information: date; amount of the payment; the individual's name, permanent address, and a unique identifier number^{**}; the title of the research project; and the project grant number if the research project is supported by extramural funds to the university.

In some cases, payments to research subjects must be made by check (e.g., when the research subject participates in a telephone survey, when a small number of research subjects are to be paid large sums). In this case, the PI should prepare and submit to the Office of Research and Sponsored Programs (ORSP) a disbursement voucher form, available from the Controller's Office website, for each payment. Checks will be made payable to the research subject and mailed directly to the research subject's mailing address (P.O. boxes are not acceptable).

The PI, due to security issues or convenience, may prefer to pay the research subjects with a gift (e.g., a Tee shirt, tote bag) or a gift card. Gifts and gift cards in small denominations can be purchased from a vendor using a university Pro Card or by processing a vendor invoice. The

^{**} Acceptable identifier numbers include the research subject's social security number, taxpayer identification number, driver's license number, or passport number.

gifts and gift cards must be treated the same as cash – adequate controls and security must be provided, and the required recipient information on a receipt specifying the value of the gift must be collected as described previously.

When the research project is finished, the PI must return to ORSP all original receipts signed by the research subjects, and a summary memo. The summary memo should include the PI's name, contact information, and signature; the research project title and project grant number (if applicable); a brief description of the research activity (e.g., completion of a 50-item survey questionnaire); and a summary of the receipts (e.g., 30 payments of \$10 each = \$300, cash advance = \$400, cash returned \$100). If not all the money the PI received in the cash advance or not all of the gifts and gift cards purchased by the PI are disbursed to research subjects, then the PI must reimburse the project grant by depositing a personal check equal to the cash balance or the value of the remaining gifts and gift cards, made out to the university, into the project grant account. In cases where the PI does not provide proper documentation to account for expenditures, the cash advance or value of the gifts and gift cards will be considered taxable income to that PI.

The PI must keep all payment records (e.g., duplicate receipts, code identifier list, summary memo) for audit purposes in the research project records for the current year plus 7 years after the close of the research project for federally-funded projects, or the current year plus 3 years for non-federally funded projects.

How can payments to research subjects be made and still maintain confidentiality of subject information?

If the names of the research subjects must be kept confidential in accordance with the IRB-approved research protocol, then the PI must prepare and submit to the Controller's Office for approval a payment process plan that meets internal control guidelines. The plan must explicate how the payment process will maintain confidentiality while meeting Internal Revenue Service (IRS) reporting requirements and conforming to the university's standard accounting and payment practices. For example, duplicate receipts can be prepared and submitted using code identifiers in place of the research subject's name and contact information, and the research subject can provide initials or just a first name rather than a complete signature. The PI must maintain the signed receipts together with a file of the complete contact information that cross-references the code identifier on the duplicate receipt given to each research subject. A certification statement should be attached, signed by the PI and stating that: "Details on the process used to pay research subjects are on file in the PI's department and available for audit."

Can UMass Boston employees be paid for participation as a research subject?

University employees, including undergraduate or graduate student employees, may not be paid to participate in a research project. Moreover, university employees generally should not be included as participants in research projects conducted by UMass Boston PIs. The IRB administrator in ORSP is available to consult with PIs on the question of employee participation in research projects.

Is the payment to a research subject taxable income?

Payments to a research subject (cash as well as gifts) are considered taxable income by the IRS. The university will report research subject payments to the individual on IRS Form 1099-Misc at the end of each year according to university policy.

Richard F. Antonak
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