

An IRB Resource for Investigators

Practical Points to Consider: Payment to Research Participants

Intended Use

This document was created as a resource for IRBs and HRPPs to adapt and use when developing guidance for investigators on payments to research participants.¹ This guidance is intended to be reviewed by IRBs and HRPPs in advance of dissemination to investigators so it can be aligned with institutional policies. This document provides an overview of why investigators and sponsors should consider providing payments to research participants, the different types of payment, the tax implications associated with each (with specific reference to current US regulations), and suggests appropriate forms of communication with research participants regarding payment.

Paying Research Participants

While there are historical concerns about paying research participants, consensus is growing among researchers, reflected in the literature, about the importance of offering payment to participants.^{2,3} This information sheet will not repeat the arguments, discussion, or suggestions for offers of payment in clinical research, including a drive to increase inclusion and fairness,^{4 5 6} but will focus on practical approaches to implement a framework for ethical payment to participants.

Types of Payment

The list below provides a summary of different types of payments that may be made to a research participant. In general, the term **payment** is inclusive of, but not restricted to, those listed below:

¹ Additional guidance on the topic can be found in Chapter 13.6 of the MRCT Center's *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document. Available online: <https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/>

² Largent EA, Lynch HF. Paying research participants: the outsized influence of “undue influence”. IRB. 2017 Jul;39(4):1.

³ Largent EA, Lynch HF. Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward. Yale journal of health policy, law, and ethics. 2017;17(1):61.

⁴ Gelinas L, Largent EA, Cohen IG, Kornetsky S, Bierer BE, Fernandez Lynch H. A framework for ethical payment to research participants. N Engl J Med 2018; 378:766-77. DOI: 10.1056/NEJMs1710591.

⁵ Gelinas L, White SA, Bierer BE. Economic vulnerability and payment for research participation. Clinical Trials. 2020 Jun;17(3):264-72.

⁶ Bierer BE, White SA, Gelinas L, Strauss DH. Fair payment and just benefits to enhance diversity in clinical research. Journal of Clinical and Translational Science. 2021;5(1).

Payment Type	Definition	Example
Reimbursement	Re-payments to research participants to cover expenses that they incur while participating in clinical research.	<p>Transportation/travel reimbursement, i.e., taxi/transport fare, parking fees, mileage per standard national rates, food, and accommodation.</p> <p>Direct booking and payment for a flight or hotel room for participant's on-site stay.</p> <p>Direct provision of a parking sticker or meal voucher.</p> <p>Incidentals costs, such as childcare, elderly care, additional medical expenses incurred only as part of research participation.</p>
Compensation	Cash or cash equivalents provided to research participants as fair value compensation for their time and research-related efforts and burdens.	Checks, gift cards, headphones, in-kind items (e.g., books), etc.
Tangible Gift	Items of nominal value (e.g., \$100 or less) given to a research subject as a token of gratitude for participation. The institution generally sets the threshold for consideration of a nominal payment.	Provisional gift such as a study device (e.g., physical fitness tracker) or gift (e.g., a water bottle, calendar) that a participant can keep after use.
Incentive	Payments offered, in addition to and/or in place of reimbursement or compensation, to encourage recruitment, participation, retention, and study completion.	Sign-on "consent" bonus; study visit payment; "completion" payment

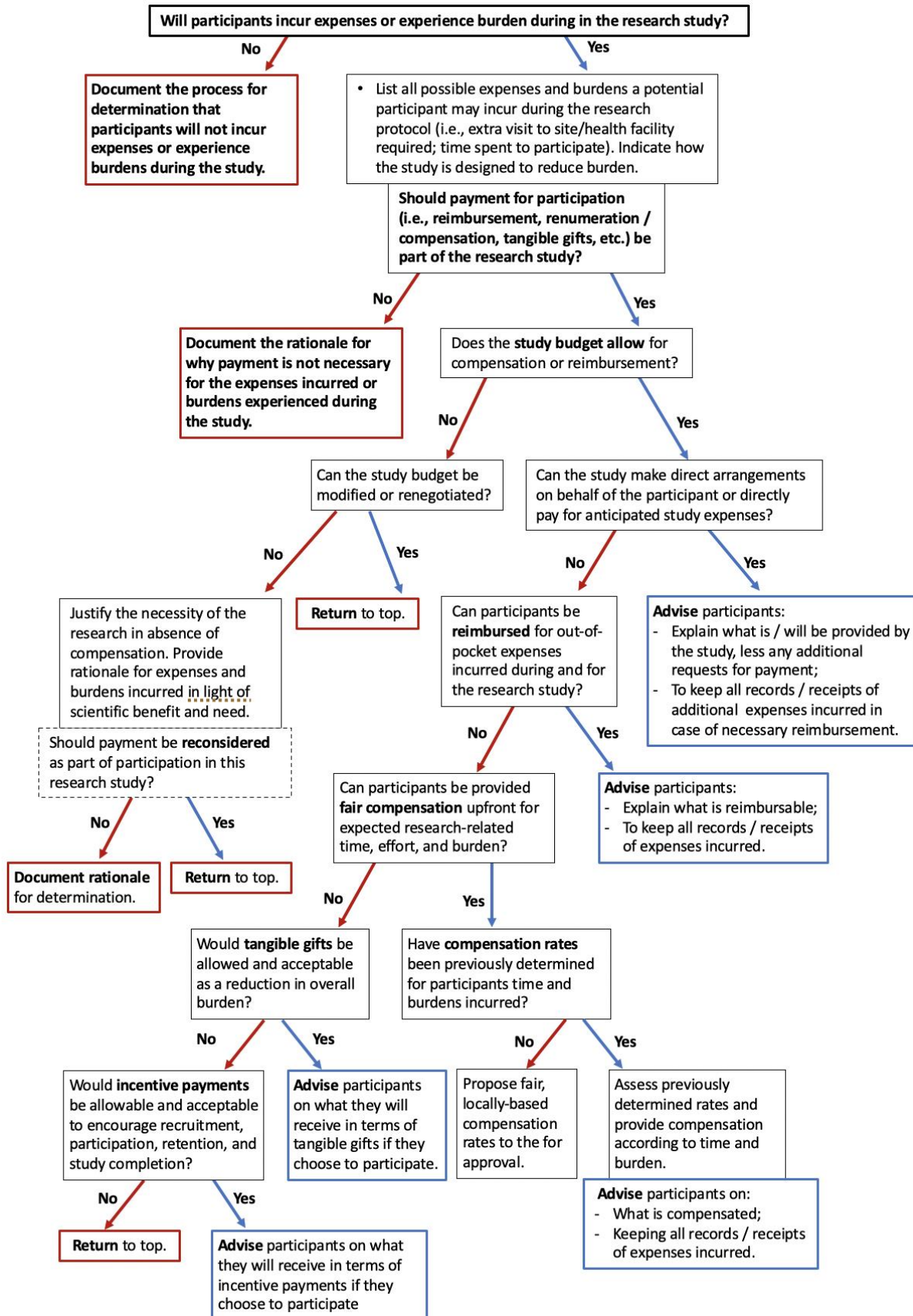
Certain types of payments raise important ethical considerations. Paying participants to recruit their friends and associates, so called "referral fees," can be problematic and should be carefully reviewed by the IRB. In some cases using "referral fees" might be an important way to connect with hard to reach populations. But an IRB might want to limit the number of "referral fees" a participant can receive. Similarly, incremental payment for certain activities (e.g., consent for additional biopsies, interventions beyond those required for the research, or sub-study components) should be described as 'optional' study interventions with separate payments that will need to be explained in full detail.

Considerations for Investigators Proposing Payment Offers

Always read and understand the your institution's organizational policies, guidelines, and/or standard operating procedures regarding payments to participants. In addition, read and understand requirements outlined in the sponsor and/or funder agreement.

Generally, reimbursement to participants is a best practice for all research studies, and should be itemized with as much detail as possible so as not to neglect potential costs of participation. Reimbursement for reasonable expenses incurred by research participants restores participants to their financial baseline before participation. As such, rationale for payment and the amount should be appropriately considered and clearly described in the informed consent form, and subsequently approved by the IRB consistent with institutional policy. In some cases, the IRB may request payment amounts be rationalized and itemized according to the categories mentioned above in Table 1.

In instances where payment is not possible or not offered by the study, it is best practice to document the reason and provide rationale for as to why. **To aid investigators in determining the best form of payment for participants, the following decision tree is proposed:**



Important considerations to safeguard participants

- *Payment and research-related injury:* When possible, offer options for payment coverage for participants (e.g., insurance, other mechanisms of financial protection) to compensate for reasonable expenses arising from research-related injury.⁷ If no payment for research-related injury is possible, clarify in the informed consent document and process.
- *Payments and participant comprehension:* When compensation, or incentives (e.g., consent ‘signing bonus’ or study completion bonus) are offered, safeguards to validate and ensure the participants’ understanding of the research should be instituted within the informed consent process, especially as payment amounts increase. Include, when appropriate, measures to assess understanding (e.g., having participants explain key aspects of research in their own words, “teach back”).⁸
- *Payments and undue influence:* Payment as a recruitment, retention, or completion incentive should be offered as an additional incremental payment when compensation or reimbursement are already in place. Offering an incentive payment as a singular payment feature for recruitment, retention, or study completion can be controversial and should be justified.
- *Payments and risk of eligibility to entitlements:* Unanticipated consequences of payment to participants must be considered and, optimally, should be explained to the participant in advance of their receipt of payments. Availability of institutional resources (e.g., financial services) should be considered prior to giving any tax advice to participants, and we advise consulting an expert in local tax requirements. In the US, for example, the Supplemental Security Income (SSI) is a US government means-tested welfare program that provides cash assistance and health care coverage to people with low income and to those with limited assets who are older than 65, blind, or have a disability. SSI and Medicaid currently **exclude the first \$2,000 of income per year** in the calculation of eligibility, but restrictions apply (currently for certain clinical trials studying treatments for rare diseases and not for other diseases.) Another example is the Supplemental Nutrition Assistance Program (SNAP) program in which benefits are reduced by amount of monthly income. Provision of payment for research participation may jeopardize eligibility for federal and state programs as eligibilities differ by family size, threshold amounts, and other considerations. These potential risks should be disclosed and discussed in advance with the participant.

⁷ Gelinas L, White SA, Bierer BE. Economic vulnerability and payment for research participation. *Clinical Trials*. 2020 Jun;17(3):264-72.

⁸ Gelinas L, Largent EA, Cohen IG, Kornetsky S, Bierer BE, Fernandez Lynch H. A framework for ethical payment to research participants.

Tax Considerations*

Note: The following is intended to be general considerations regarding the tax consequences of payment for research participation. It is not tax advice. Individuals should seek tax advice from professional advisors, certified public accountants, and should always consult institutional policies, requirements, and guidance on tax reporting.

Overall, **any payment is typically considered taxable income to the research participant**, regardless of the dollar amount. Reimbursement for documented expenses may be the exception and unless directly organized, booked, and paid by study staff, documentation of expenses should be retained by the participant.

The tax rules that apply to US citizens and permanent residents (i.e., “US National,” or “Resident Alien,” the latter defined not as a US citizen but a lawful permanent resident or one who meets either the green card test or the substantial presence test for the calendar year)⁹ differ slightly from the rules that apply to Nonresident Aliens (see [IRS Publication 519](#) (2020) US Tax Guide for Aliens). Therefore, rules that apply to reimbursements, compensation, and/or tangible gifts differ; the tax implications of each should be considered by the investigator, grant administrator, and institutional support staff in advance of study start-up.

The IRB, investigator, and sponsor/CRO should be aware of and abide by all tax legislation for the differing situations and procedures in each case. This is often handled by a research management personnel and their advice should be sought. The summary below reviews tax consequences for the different research payment types under US federal law for Nonresident Aliens and US citizens.

US Citizens, Permanent Residents, Resident Aliens

Per US [Internal Revenue Service](#) (IRS) requirements, if payments made to a US citizen or permanent resident from an institution total \$600 or more in a given calendar year, the IRS requires that the institution report that amount on a [Form 1099-MISC](#). The IRS does not require the institution to report payments less than a total of \$600 in a given calendar year; however, research participants should be advised to report all payments on their individual income tax returns and should be directed to consult with their own tax advisors regarding these reporting requirements.

⁹ F and J student visa holders are considered resident aliens after five calendar years in the US. Scholars in J status are generally considered nonresident aliens for tax purposes for the first two calendar years of their stay in the US.

Compensation (see definition in Table 1 above) as advance payment of “estimated expenses” that are not based on receipts or actual costs incurred may be considered taxable income.

- Exception: Advance payment of expenses is not considered taxable income if the subject provides documentation/receipts after incurring the cost and returns all excess payment.

Reimbursement (see definition in Table 1 above) of actual expenses based on receipts is generally not considered taxable income.

- Reimbursement for expenses may be made if the participant provides a receipt of the expense. The institution should establish its SOP for participant reimbursement process.
- Direct payments on behalf of the participant incurred by an investigator and/or institution on behalf of the participant (e.g., booking and paying for a participant’s flight or hotel stay; provision of a parking sticker, transportation, or meal voucher) are generally not considered taxable income. The investigator must retain documentation or receipts that reflect why the payments were made. Such direct payments are encouraged, where possible, to avoid complicated reimbursement requests from participants (such as in the case of significant expenses like flights and hotels) or numerous small reimbursement requests (such as for parking or meals).

Tangible gifts (see definition in Table 1 above) that are given to research participants (e.g., a toy for a child participant, a calendar, a water bottle) are generally not considered taxable income to the participant. To ensure compliance with tax reporting requirements, each institution should establish their tangible gift value limit and a process for granting exception to that limit (if desirable).

Nonresident Aliens

Regardless of dollar amount, payments to nonresident, foreign nationals may be taxable income to the research participant. The extent to which these payments are taxable varies depending on the circumstance; there are certain [US Visa classifications](#) that prohibit any payment beyond what is specifically allowed under that US Visa. In addition, some nonresident aliens may receive tax benefits under [tax treaties](#) with certain foreign countries. More specific instructions should be sought from a tax advisor.

Procedures

To ensure that any payment to US citizens, permanent residents, and resident aliens is appropriately reported to the IRS in accordance with these requirements, it is important for institutions to develop Standard Operating Procedures (SOPs) and/or policies with regard to local, state and federal laws as applicable, including setting threshold values for one-time payments, multiple payments, etc.

Communicating with Research Participants

Investigators should not provide or attempt to provide tax or US visa advice and should suggest that potential research participants seek their own independent advisors in these areas.

Investigators should inform potential participants before and during the consent process of any payment that they may receive as a consequence of participation in the research study. Because reporting obligations and tax considerations may affect individuals' decision to participate and the means by which independent advice can be sought may be limited, the investigator should clearly inform the individual about reporting requirements (including the collection of SSN/ITIN information) and potential tax consequences (including the responsibility of the institution (or payer) to issue a Form 1099-MISC if they receive payments equal to or greater than \$600 in a given year). If the individual does not have, or wishes not to provide their SSN/ITIN, they may decline participation in the study or decline payment. The investigator should document the participant's decision accordingly.

Table 2 below offers suggested language to include in the informed consent process and, if applicable, in the informed consent form based on the tiered structure for tracking of payments. Organizational policies may establish requirements for tracking payments to participants and, as a result, may impact the language used in the informed consent form. Note that payment threshold values are for demonstrative purposes and are not to be interpreted as prescriptive.

Table 2: Example language to use in consent process and, if applicable, in the informed consent form.

Payment Threshold For Individual Participants	Tracking Requirements	Suggested Informed Consent Language
\$50 or less	Internal tracking at the grant administration / departmental level	<i>Please be aware that any payments for participation in research studies may be considered taxable income. Please record and track any payments you may receive as part of participating in this study for your own records.</i>
\$50.01-\$599.99	Internal tracking at the grant administration / departmental level	<i>Please be aware that any payments for participation in research may be considered taxable income. The <Organization> requires tracking payments to you; this may include your name and contact information. This information is stored confidentially and separately from research data. If you receive \$600 or more in a calendar year from this institution, you may be contacted to provide additional information (e.g., Social Security Number) for tax reporting purposes.</i>

<p>\$600 or greater</p>	<p>Participant needs to complete applicable IRS Form(s) for annual tax reporting</p>	<p><i>Please be aware that payments for participation in research may be considered taxable income. <Organization> requires tracking payments to you, including your name and contact information. Because you will receive \$600 or more in a calendar year, you will be asked to provide additional information (e.g., Social Security Number or Individual Taxpayer Information Number) for tax reporting purposes. This information is stored confidentially and separately from research data and will be reported at the end of the year to the US IRS.</i></p>
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Adapted from University of Oregon: <https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/compensation-participation-research#4>

Confidentiality

Investigators should be reminded that SSNs/ITINs are confidential, sensitive, and identifying information about an individual. Best practices for investigators include maintaining records/documents containing SSNs/ITINs confidentially in (1) locked files and not storing them electronically, or (2) password-protected and secure electronic systems. Investigators are reminded to redact or remove SSNs/ITINs from study records. Investigators should refer to their institution’s policies regarding the storage, maintenance, and security of Personal Information and Protected Health Information for additional guidance.