THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

# *Policy on Remuneration in Research Studies*

## PURPOSE

The purpose of this policy is to establish principles, guidelines and requirements for The University of Texas MD Anderson Cancer Center (MD Anderson) Institutional Review Board (IRB) review and approval of research studies that include remuneration of human subjects.

## POLICY STATEMENT

The IRB must assure that appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB will review all of the research documents and activities that bear directly on the rights and welfare of the participants in the proposed research, including plans proposed for remuneration of participants. The purpose of this policy is to describe the requirements for the appropriate remuneration of research participants.

## SCOPE

This policy applies to all human subjects research conducted at MD Anderson.

## DEFINITIONS

**Remuneration:** Any payment received for participation in a research study. For a given study, the sum of reimbursement, outcome incentive payments and other payments is equal to the remuneration.

**Reimbursement:** Cash or cash equivalents given to study participants to defray actual out-of-pocket expenses of participation such as transportation, parking or hotel stays. Receipts for out-of-pocket expenses may be required.

**Outcome incentive payments:** Cash, cash equivalents, or non-monetary items given to participants for achieving desired outcomes such as smoking cessation and weight loss. Outcome incentive payments are considered a part of the treatment plan. Amounts exceeding a specific threshold in a single calendar year are reportable to IRS as income.

**Other payments:** Cash, cash equivalents, or non-monetary items given to study participants for time spent, inconvenience, or discomfort. Amounts exceeding a specific threshold in a single calendar year are reportable to IRS as income.

**Cash or cash equivalents:** Cash, check, parking, housing or transportation vouchers, debit cards.

**Non-monetary items:** Items of value that could include t-shirts, mugs, tote bags, exercise equipment, etc.

**Influence:** Factors that would normally be considered and weighed in an informed decision and which might guide the appropriate decision for an individual or group. Influence is a motivation that does not interfere with the voluntariness of a decision. For example, information about the benefits and harms of a treatment appropriately influences decisions to participate in research.

**Undue influence/inappropriate inducement:** An offer of an excessive or inappropriate reward that is difficult to resist and that 1) motivates one to act in a manner contrary to one's good judgment or intentions, 2) impedes one's voluntary choice or 3) compels one to take unnecessary or unreasonable risks. In practice, undue inducements are problematic because: (1) offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and (2) they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling — or continuing — as participants in a research project.

## PRINCIPALS

Remuneration of participants without IRB approval is prohibited. The objective of remuneration is to ensure to the extent possible that participants are no worse off than if they had not participated in the research. To that end, the following principles will guide IRB review of participant remuneration and should be used by investigators to design remuneration plans.

- The value of remuneration must not be so large that it could unduly influence a person to participate in the research or to continue participation when it is not consistent with their values and interests. The IRB will be the arbiter for whether the remuneration is considered too large.
- The value of remuneration is determined by its potential impact on the specific population targeted; studies recruiting vulnerable populations will receive additional scrutiny. The examination of the potential for undue influence will receive additional ethical scrutiny in the case where participants are children. This applies whether payments are received by the child participant or the parent or legally authorized representative.
- Remuneration must not affect the equitable selection of participants. Remuneration should not be unnecessarily restricted or minimized, thereby making participation impossible for economically disadvantaged persons or other population groups.
- Remuneration should be commensurate with the amount of time, inconvenience, or discomfort involved in participating in the study and with the actual out-of-pocket expenses incurred.
- Remuneration must accrue as the study progresses and not be contingent on study completion. Prorated payments must be made regardless of withdrawal from the study.
- Payments should be equitably distributed to all participants (equal payment for equal participation, out-of-pocket expenses, or outcomes achieved).
- Remuneration plans must be clearly described in the protocol and informed consent document. Changes in the originally approved plan must be submitted to the IRB for approval prior to implementation.

- Payment to physicians or staff in exchange for referral of potential participants and payment tied to the rate or timing of enrollment (e.g., a bonus payment) is prohibited.

The IRB also will consider the following issues in its deliberations.

- The risk of harm and potential for benefit to the individual participants
- The amount of time, inconvenience, or discomfort experienced by participants that is over and above that experienced by similar people who are not participating in the research
- Study population (e.g., MD Anderson patient population, public registry, relationship to investigator)
- The inclusion or absence of vulnerable populations (particularly children or socioeconomically disadvantaged people)
- The remuneration amount, currency/types, proration, payment schedules, distribution plans and the effect of withdrawal on remuneration.

**Determining the Amount of Remuneration**

The amount of remuneration should be based on the incremental time, inconvenience and discomfort associated with participation in the research (compared with not participating) or the actual out-of-pocket expenses. It is appropriate to provide participants with higher payments for larger amounts of time, more inconvenience (e.g., strategies that require participant responses throughout the day, or requiring travel to distant study sites), and more discomfort (e.g., blood draw vs. bronchoscopy). It is acceptable to study the effect of various amounts of outcome incentive payments in the research setting. The value of other payments to the target population will be carefully considered with emphasis on avoiding undue influence to vulnerable participants, in particular economically disadvantaged people and children. Other payments must not be so large that they result in disproportionate representation of vulnerable people (e.g., homeless or very low income populations). Debit cards and non-monetary items will be assessed based on their cash value.

**Lotteries**

Based on the principle of equity, lotteries or drawings are discouraged. It is preferred that a payment be distributed evenly among all participants. In the case where a lottery is critical to the success of the study, the plan must comply with applicable state laws.

**Prorating Remuneration**

Remuneration should be prorated such that payments are commensurate with participants' actual out-of-pocket expenses (in the case of reimbursement) or with participants' completion of specific study tasks or milestones (in the case of other payments). For example, a study providing payments for completion of surveys on three occasions should provide partial payment for completion of each survey in the case where a participant withdraws or fails to complete all three surveys. Partial payments need not be equal, but should be commensurate with the time or inconvenience at each milestone. Prorated payments are appropriate for all study tasks or milestones, including blood draws, medical procedures (e.g., colonoscopies), questionnaires, telephone interviews and/or computer-administered assessments. It is acceptable to provide a payment for each assessment commensurate with the time, inconvenience, and discomfort involved in completing that assessment.

**Timing of Remuneration**

Payments should be provided within a reasonable time after the expense is incurred or a milestone is completed. However, it is acceptable to hold the payments until the end of the study, as long as the participants were clearly informed of the payment plan at the time of recruitment. In any case however, remuneration cannot be made contingent on the participant completing the study, but should be made commensurate with the time or duration of participation as described in the protocol plan.

**Describing Remuneration in the Informed Consent Document and Protocol**
In the case of studies that offer reimbursement for out-of-pocket expenses, allowable expenses and caps on expenses, required documentation of expenses, and the expected timing of reimbursement should be described in the informed consent document and the protocol.

In the case of studies offering outcome incentive payments, the amount of the payment, the currency or form of payment, the distribution schedule, the method by which a successful outcome will be demonstrated, and the effect of withdrawal on payments should be clearly stated in the informed consent document and in the protocol. The informed consent document must clearly state that participants will not receive the outcome incentive payment if the desired outcome is not achieved. If the total outcome incentive payment may exceed the threshold for reporting to IRS, this requirement and the required collection of Social Security number and other private information by MD Anderson for such purposes should be described in the informed consent document and the protocol.

In the case of studies offering other payments, the amount per visit/task and details of proration, currency or form of payment, total payment amount, the distribution schedule, and the effect of withdrawal on payments should be clearly stated in the informed consent document and the protocol. If the total other payments may exceed the threshold for reporting to IRS this requirement and the required collection of Social Security number and other private information by MD Anderson for such purposes should be described in the informed consent document and the protocol.

Distribution of payments must be documented in the permanent study records. Procedures for distribution and documentation of payments must be clearly described in the protocol or appendices. If IRB approved standard operating procedures for distribution or documentation of payments are employed, it is acceptable to reference these in the protocol and it is not necessary to include these as attachments in the protocol.

Except in the case of outcome incentive payments, it should be made clear in both the informed consent document and in the protocol that payments are compensation for time, inconvenience, and discomfort only.

Recruitment materials and the informed consent document must not promise the total amount in the case where remuneration is prorated per visit/procedure. Instead, the proration schedule should be explained along with the maximum total amount that may be received.

**Data Collection Relating to Participant Use of Remuneration**
Some forms of remuneration may have electronic systems in place that allow for tracking of distribution and use. Before investigators are allowed to run or request reports on participants' use of remuneration, a request will need to be submitted to the IRB for review and approval. The investigator will need to provide adequate justification for the use of such data.

## REFERENCES

21 CFR 50
21 CFR 56
21 CFR 312
21 CFR 812
45 CFR 46
ICH GCP 4.5

MD Anderson Informed Consent Policy (CLN0547)

## REVISIONS

| Date | Action | Initials | Description |
|---|---|---|---|
| 01/22/2014 | Approval | JC | Institutional Review Board 3 (IRB3) Review |
| 06/27/2019 | Rev | JH | Updated format |
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