HRP-316 | 3/29/2024

WORKSHEET: Payments

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating payments to subjects or their Legally Authorized Representatives.[[1]](#endnote-2)

1. Requirements for Payments[[2]](#endnote-3) (Check if “Yes”. All must be checked)

All payments are described in the protocol including: (Check if “Yes”. All must be checked)

Amount

Method

Reason/purpose (e.g., their time, inconvenience, discomfort, or some other consideration)

Timing of disbursement

Credit for payment accrues as the study progresses.

Payment is not contingent upon completing the entire study.

The amount of payment and the proposed method and timing of disbursement is neither coercive nor presented undue influence. Participants should be paid in proportion to their time and inconvenience as a result of participation in the research study.[[3]](#endnote-4)

Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn and is evaluated in context of any reimbursement or compensation payment included in the study. The IRB generally does not approve completion bonuses that exceed 10% of the total compensation of the study or no more than $100.[[4]](#endnote-5)

All information concerning payment, including the amount and schedule of payments, is in the informed consent document.

Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved.

If the payment involves a random drawing, the requirements in Section 2 have been satisfied.

2. Random Drawings Requirements[[5]](#endnote-6),[[6]](#endnote-7) (Check if “Yes”. All must be checked.)

The research activities present no more than Minimal Risk to Human Subjects.

The random drawing will not create undue influence on a potential participant’s decision to volunteer to participate in the research activities.

The investigator has provided satisfactory rationale that the compensation by random drawing is necessary to gather sufficient data to address the research question.

The investigator has provided satisfactory justification that Human Subjects cannot be compensated on an individual basis.

The investigator has provided satisfactory justification that unequal distribution of compensation is fair to those who will not receive compensation (i.e., burdensome or stressful research might make unequal distribution seem unfair to participants).

The consent process and documentation include an explanation of the potential odds of receiving the random compensation (probability of winning, if known).

1. This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E [↑](#endnote-ref-2)
2. FDA Information Sheet, “Guidance for Institutional Review Boards and Clinical Investigators, Payment and Reimbursement to Research Subjects” January 2018. [↑](#endnote-ref-3)
3. Investigators planning to use MTurk for recruitment purposes are expected to outline an equivalent hourly rate for participants in the study. If offering less than an hourly rate per the current definition of a living wage (see https://livingwage.mit.edu/counties/27053), the investigator must provide a justification to the IRB for review. [↑](#endnote-ref-4)
4. Payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. This does not include reimbursement payments, which are based on expenses incurred from study participation. [↑](#endnote-ref-5)
5. The University of Minnesota Office of the General Counsel was consulted in the development of this guidance and confirmed that there are no MN State Laws that apply to the use of random drawings in research. [↑](#endnote-ref-6)
6. MN law (Minnesota Statute 349.181) prohibits minors from participating in various forms of gambling, including raffles/lotteries. The drawings covered under the IRB policy/guidance do not meet the legal definition of gambling (and therefore may be conducted legally without a license or permit) because none of the subjects "give consideration" (i.e., pay money) for a chance to win the prize. Subjects under 18 could participate legally in these incentive drawings, because the drawings are not gambling. [↑](#endnote-ref-7)