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

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

Amount

Method

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.

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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn and is evaluated in context of any reimbursement or compensation payment included in the study.

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.

The study team is to provide the UCI Office of Accounting and Fiscal Services the name and social security number of participants who receive payments more than $600 per calendar year preferably on Form W-9 for processing the Form 1099-Misc to be forwarded to the IRS.

The IRB will determine whether lotteries, raffles, and/or drawings may be used to recruit or retain participants. For the IRB to consider approving the use of lotteries, raffles, and/or drawings, the following must be considered:

The study involves minimal risk to participants (Exempt or Expedited).

The prize is less than $600 and will not unduly influence participation in the research.

The subject compensation process must include the following:

Procedures to ensure that any individual who is asked to participate in the research study but declines, who consents/assents to enroll in the study, or who fails to complete the study, will be given equal compensation by having an equal chance of winning. In other words, if an individual is eligible to participate in the study, and therefore the lottery, raffle and/or drawing, they are not required to participate in the study to be eligible to participate in the lottery, raffle, and/or drawing;

Procedures for the inclusion of an individual who is not asked to participate in the study but wishes to be included in the lottery, raffle, and/or drawing;

A fair method of choosing the winner and how the winner will be notified; and

Disclosure of the approximate chance of winning (e.g., no less than 1 in 1000) in the consent/assent.

1. FDA Information Sheet, “Guidance for Institutional Review Boards and Clinical Investigators, Payment and Reimbursement to Research Subjects” January 2018. [↑](#endnote-ref-2)