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| 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. This worksheet is to be used. It does not have to be completed or retained. | | |
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| 1. Requirements for Payments (All must be “Yes” or “N/A”) | | |
| Yes  No | All payments are described in the application or protocol including: | |
| Yes  No | Amount |
| Yes  No | Method |
| Yes  No | Timing of disbursement |
| Yes  No | Credit for payment accrues as the study progresses. | |
| Yes  No | Payment is not contingent upon completing the entire study. | |
| Yes  No | The amount of payment and the proposed method and timing of disbursement is neither coercive nor presented undue influence. | |
| Yes  No  N/A | 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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. (N/A if no completion bonus.) | |
| Yes  No | All information concerning payment, including the amount and schedule of payments, is in the informed consent document. | |
| Yes  No | Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved. | |
| Yes  No  N/A | If participants will be compensated for their time, there is a statement telling the participant that a W-9 will need to be completed in order to receive payment, and that the payment may be considered taxable income according to the IRS. | |
| Yes  No  N/A | If participants will be reimbursed for items related to research participation (i.e. mileage, parking, hotels, food,etc.), the reimbursement is not taxable and it is not necessary to have W-9 language in the ICF. | |
| Yes  No  N/A | If identifiable information will be disclosed to a 3rd party for the purpose of establishing an account that will facilitate payment to subjects, the subject must first authorize this disclosure via a HIPAA authorization for reimbursement purposes (see worksheet HRP-310 for required elements of authorization) | |