

## WORKSHEET: Payments

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This worksheet is used to determine whether non-exempt <Human Research> using payments can be approved.

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All criteria in 2 must be met. All criteria in 3 must be met for clinical trials.

### 1. The following has been reviewed

- 1.1 ● The amount of all payments
- 1.2 ● The method of all payment
- 1.3 ● The schedule of all payments

### 2. Criteria for approval of payments *45 CFR §46.116 and 21 CFR §50.25*

- 2.1  The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence
- 2.2  Credit for payment accrues as the study progresses and is not contingent upon the subject completing the entire study
- 2.3  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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn (see Footnote 1)
- 2.4  All information concerning payment, including the amount and schedule of payments, is set forth in the consent document

### 3. Additional criteria for approval of an advertisement for clinical trial

- 3.1  Payment does not include a discount on the purchase price of the product once it has been approved for marketing

### 4. Notes

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### 5. Footnotes

- 5.1 Payment of a small proportion as an incentive for completion of the study is acceptable, providing that such incentive is not coercive.