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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** (Check if **“Yes”**. All must be checked) | | |
| **☐** | All payments are described in the consent document including:(Check if **“Yes”**. All must be checked) | |
| **☐** | Amount |
| **☐** | Method |
| **☐** | Timing of disbursement |
| **☐** | Payment to study subjects accrues as the study progresses and is not contingent upon the subject completing the entire study. (If not checked, both of the following must be checked)  ☐ The study involves less than four visits  ☐ Continuation in the study will not result in pain, discomfort, significant inconvenience or include procedures that involve greater than minimal risk.[[1]](#footnote-0) | |
| **☐** | The amount of payment and the proposed method and timing of disbursement is neither coercive nor unduly influential[[2]](#footnote-1)l | |
| **☐** | 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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. | |
| **☐** | Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved. | |

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1. [OHRP Guidance](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html) recommends that payment should be prorated for the time of participation rather than delayed until study completion when the study is of considerable duration or involves multiple interactions or interventions. [FDA Guidance](https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm) states the amount and timing of payment shouldn’t unduly influence subjects into remaining in the study when they would otherwise have withdrawn. [↑](#footnote-ref-0)
2. Coercion is rare. Examples include an inmate whose care and treatment might be compromised for refusing participation or a Patient may participate in a study run by his or her physician because of the fear or reality that care is contingent on participation. Examples of undue influence include an offer one cannot refuse, a controlling and irresistible influence, and influence strong enough to compel someone to participate against their interests. (NIH presentation, [Ethical and practical considerations of payment research participants](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=2ahUKEwjW9b-x767eAhUDCXwKHR2LAn8QFjAEegQICBAC&url=https%3A%2F%2Fwww.niehs.nih.gov%2Fresearch%2Fresources%2Fassets%2Fdocs%2Fethical_and_practical_considerations_of_paying_research_participants_508.pdf&usg=AOvVaw010Tqum9s7y1GWOa7oteks)). [↑](#footnote-ref-1)