



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

What is Undue Influence in Research?

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Undue Influence vs. Coercion

- **Undue Influence** - influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences
- **Coercion** – the practice of persuading someone to do something by using force or threats



The following could potentially create undue influence by one party over another:

- Teacher – Student
- Employer – Employee
- Doctor – Patient
- Lawyer – Client
- Parent – Child
- Prison Guard – Prisoner



Incentive (Also: Compensation)

- A form of payment offered to an individual in exchange for time and effort or to offset costs of participation (e.g., travel to study site)
- Payment can be in any form, including but not limited to, gift cards, check, cash, and course credit/extra credit



There is Undue Influence in Research if:

- Incentive offer is so excessive or enticing that it compromises evaluation of important study features such as risks, burdens, and discomfort
 - It impairs the participants understanding of the research and their participation in it
 - Legitimacy of informed consent is put in doubt



Forms of Payment Not Raising Concern About Undue Influence

1. Reimbursement

- E.g., transportation, parking, lodging, childcare, additional medical expenses, meals outside the home (any out-of-pocket costs)

2. Compensation

- To compensate participants for their time and effort
 - Average working wage and purchasing parity ratio in the community where the research is being conducted

3. Appreciation

- To thank participants for their contribution
 - Small payments or gifts not intended to meaningfully reimburse or compensate participants



Requirements for Incentives/Compensation

1. All incentives (monetary and non-monetary) are described in the protocol and consent form including:
 - Type of payment (e.g., cash, check, gift card, services without charge, extra class/course credit)
 - Amount (or cash value if non-monetary; the number of credit unit/s);
 - Payment schedule, if applicable
2. Incentive is commensurate to the time and inconvenience as a result of participation in the study
 - Amount is reasonable in the context of the study procedures, targeted population, and risk/benefits
3. Provision of incentives is not contingent upon completing the entire study
 - Incentive/compensation accrues as the study progresses (the scheme for pro-ration for multiple sessions or procedures)



Requirements for Incentives/Compensation (cont.)

4. Payment is not described as a “benefit” of research participation
5. The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence
6. 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
7. For FDA-regulated studies (devices or drugs), compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing
8. There are no bonus payments or incentives for study staff for recruiting others



Things to Consider:

- The study involves compensation for activities, which are an integral part of the design, but which are not incentives for participation
 - E.g., The study may involve a delay-discounting task/assessment where the subject will be paid according to his/her choices during the task
- The incentive scheme is a drawing and can be allowed:
 - If the general public is allowed to participate without being required to pay or do anything (no consideration)
 - So long as entry into the prize-drawing is by mail or by email (no requirement to come to a certain place or jump through any particular hoops)
 - If these requirements are not feasible, the researcher must obtain a license to conduct a raffle from the county and abide by the post-raffle reporting requirements
- All information concerning incentive/compensation, including the amount, schedule of payments, and information related to tracking/recording the payment, if applicable, is in the protocol and informed consent document

WORKSHEET - 316 - Incentives and Compensation

The purpose of this worksheet is to provide support for the convened IRB or Designated/Regulatory Reviewer when evaluating incentives/compensation to subjects or their legally authorized representatives. This worksheet is to be used. It does not have to be completed or retained.

1 Requirements for Incentives/Compensation (Check if "Yes". All must be checked)	
<input type="checkbox"/>	All incentives (monetary and non-monetary) are described in the protocol including: (Check if "Yes". All must be checked)
<input type="checkbox"/>	Type or payment method (e.g., cash/check, gift card, services without charge, extra class/course credit)
<input type="checkbox"/>	Amount (or cash value if non-monetary; the number of credit unit/s); payment schedule, if applicable
<input type="checkbox"/>	If offering extra class/course credit, describe the non-research alternative for receiving the incentive
<input type="checkbox"/>	Incentive is commensurate to the time and inconvenience <u>as a result of</u> participation in the study; the amount is reasonable in the context of the study procedures, targeted population, and risk/benefits.
<input type="checkbox"/>	Provision of incentives is not contingent upon completing the entire study. Instead, the incentive/compensation accrues as the study progresses (the scheme for pro-ration for multiple sessions or procedures). For additional information, see #1.
<input type="checkbox"/>	Payment is not described as a "benefit" of research participation on the study protocol, consent documents or other supporting materials.
<input type="checkbox"/>	The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence, i.e., incentives are not so great as to diminish the voluntariness of consent or may cause individuals to undertake risks or discomforts that they otherwise would not assume. If you come across incentives (in cash or in kind) that are seemingly large/excessive, discuss with the HSO Director.
<input type="checkbox"/>	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. If there is a large bonus for the last visit or to influence retention, discuss with the HSO Director.
<input type="checkbox"/>	For FDA-regulated studies (devices or drugs), compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
<input type="checkbox"/>	There are no bonus payments or incentives for study staff or subjects for recruiting others. (Note: if this is proposed, discuss with the HSO Director.)
<input type="checkbox"/>	The study involves compensation for activities/procedures which are an integral part of the <u>design</u> but which are not incentives for participation. For example, the study may involve a delay-discounting task/assessment where the subject will be paid according to his/her choices during the task. This should be described in the procedures/protocol, not as an incentive for participation.
<input type="checkbox"/>	The incentive scheme involves a drawing. The IRB may allow incentive-drawings associated with a research project only if the general public is allowed to participate without being required to pay or do anything (no consideration), and so long as entry into the prize-drawing is by mail or by email (no requirement to come to a certain place or jump through any particular hoops) for ALL individuals who enter in the drawing. If these requirements are not feasible, the researcher must obtain a license to conduct a raffle from the county and abide by the post-affle reporting requirements.
<input type="checkbox"/>	<input type="checkbox"/> The drawing is open to the <u>general public</u> .
<input type="checkbox"/>	<input type="checkbox"/> Recruitment materials and consent documents include a statement that participation in the research study is not required in order to enter the drawing.
	See sample review language #2.
<input type="checkbox"/>	All information concerning incentive/compensation, including the amount, schedule of payments, and information related to tracking/recording the payment, if applicable, is in the informed consent document. See sample review language #3 and #4.

Helpful Links/Resources:

- [OHRP: Attachment A – Addressing Ethical Concerns Offers of Payment to Research Participants](#)
- [UGA: HRP – 001 - Definitions](#)
- [UGA: WOKRSHEET 316 – Incentives and Compensation](#)
- [The Many Faces of “Coercion and “Undue Influence”](#)

Thank you!



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