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1. PURPOSE

1.1. The HHS regulations require that researchers seek **consent** only under circumstances that provide the prospective **participant** (or **legally authorized representative**) sufficient opportunity to consider whether or not to participate in **research** and that minimize the possibility of **coercion** or **undue influence**. The purpose of this document is to describe the University of Georgia Institutional Review Board (UGA IRB) **policy** and **procedures** for review of **research incentives** to determine whether any aspect of the proposed incentive presents coercion or undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent for participation or continued participation.

2. DEFINITIONS

2.1. **Coercion**: the practice of persuading someone to do something by using force or threats.

2.2. **Incentive**: 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. Also: **Compensation**.

2.3. **Lottery and Raffles**:

2.3.1. Georgia law defines a lottery or raffle as any scheme or procedure whereby one or more prizes are distributed by chance among persons who have either paid or promised consideration (agreed to do something in exchange) for a chance to win such prize. Such terms shall also include door prizes which are awarded to persons attending meetings or activities provided that the cost of admission to such meetings or activities does not exceed the usual cost of similar activities where such prizes are not awarded.

2.3.2. For IRB purposes, a proposed incentive plan wherein prospective research participants are offered the chance to enter a drawing to win one or more prizes is considered to be a lottery or raffle.

2.4. **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.

3. POLICY

3.1. The incentive must not be viewed as a way of offsetting risks or considered as a benefit of research participation. The amount should be commensurate to the time, effort, and/or inconvenience, not the level of risk involved in research participation.

3.2. The amount, method and timing of the proposed incentive should be just and fair. It should not create coercion or undue influence that could compromise a prospective subject's examination and evaluation of the risks or affect the voluntariness of his or her choices.



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- 3.3. All information concerning incentive should be stated in the consent document, including the amount, method and timing of disbursement.
- 3.4. Incentive should provide each participant with an equal opportunity and/or payment as similar participants in the same research procedures to avoid causing inequitable selection.
- 3.5. Provision of incentives should not be contingent upon completing the entire study because this could unduly influence a subject's decision to exercise his or her right to withdraw at any time. Payments should be pro-rated for subjects who are not able to complete the entire research study. Instead, the incentive accrues as the study progresses (e.g., for multiple sessions or studies of considerable duration).
- 3.6. The nature, value, and method of payment, should consider the context of the local economy, cultural practices, living conditions, and opportunity of earnings. These considerations apply to research conducted both inside and outside the United States.
- 3.7. Participants that are **children** may receive incentives. The amount and method of payment should be age appropriate.
- 3.8. If course credit or extra credit is offered to a student population, the researcher must offer a non-research activity that is equivalent in effort and time/duration to research participation.
- 3.9. For incentives involving **prisoners**, specific prison restrictions and requirements should be considered. See *Checklist: Research Involving Prisoners* and *WORKSHEET: Additional Federal Criteria*.
- 3.10. If the incentive scheme involves a drawing (lottery or raffle), the IRB may allow this only if the general public is allowed to enter the drawing without being required to participate in the research in order to enter the drawing. It is a felony in Georgia to conduct a lottery, raffle, or similar game of chance without obtaining a license (Georgia Code 16-12-22.1).
- 3.11. Any amount paid as a bonus for completion must be reasonable and not so large as to unduly influence subjects to stay in the study when they otherwise would have withdrawn.
- 3.12. The UGA IRB may or may not approve a **recruitment bonus** or incentive for study staff to recruit subjects, or to subjects for recruiting other subjects.
- 3.13. Researchers proposing monetary-value incentives including cash, gift card, gift items, and checks should refer to the [UGA Finance and Administration Policy for Research Participant Incentive Payments](#).
- 3.14. For FDA-regulated research, incentive for participation in a trial offered by a Sponsor cannot include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. PROCEDURES: Researchers

- 4.1. The researcher must fully describe the incentive amount and disbursement plan in the submission.
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- 4.2. The researcher is responsible for the accountability of the funds received and disbursed to research participants including departmental requirements and reporting to university business departments to fulfill federal and University policies and requirements.
- 4.3. The researcher is responsible for informing the participants in the consent process of the information needed from the subjects in order to receive the incentive as well as describe how the obtained information will be stored, used, and who will have access to it.

5. PROCEDURES: Institutional Review Board

- 5.1. The IRB Staff Member will review the submission to determine the appropriateness of the proposed incentive according to the above policy. *WORKSHEET: Incentives and Compensation* may be used for guidance.
 - 5.1.1. For **non-committee reviews**, offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.
 - 5.1.2. For committee reviews, document missing information or required modifications in the meeting minutes and in post-meeting correspondence.
- 5.2. Proposed incentive amounts and plans for disbursement that are not compliant with this policy can be discussed with the IRB Director, Assistant Director, or IRB Chairperson. The following are examples of issues that may need to be adjudicated:
 - 5.2.1. A large bonus for the last visit or to influence retention
 - 5.2.2. **Finder's fees**, bonus payments or incentives for study staff to recruit subjects or to subjects for recruiting other subjects
- 5.3. The **Designated/Regulatory Reviewer** will document determinations that the requirements of this policy have been met on the review checklist corresponding to the type of review being completed (if non-committee review) or in the meeting minutes by recording the motion to approve.

6. MATERIALS

- 6.1. WORKSHEET: Incentives and Compensation

7. REFERENCES

- 7.1. Georgia Code 16-22-22.1
- 7.2. Office of Finance and Administration Policy and Procedure: Research Participant Incentive Payments, <http://policies.uga.edu/FA/nodes/view/866/Research-Participant-Incentive-Payments>
- 7.3. Policy and Procedure: Participant Selection and Recruitment