



GUIDANCE ON PARTICIPANT INCENTIVES AND COMPENSATION IN HUMAN SUBJECTS RESEARCH

The purpose of this document is to provide guidance for researchers on the University of West Georgia Institutional Review Board (UWG IRB) 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. 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.

DEFINITIONS

- **Coercion:** the practice of persuading someone to do something by using force or threats.
- **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.**
 - **Lottery and Raffles:** In Georgia, a raffle is defined as any scheme or procedure whereby one or more prizes are distributed by chance among persons who have paid or promised consideration (agreed to do something in exchange) for a chance to win such prize ([O.C.G.A. § 16-12-22.1\[b\]\[3\]](#)). These terms 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. The State of Georgia closely regulates the operation of lotteries, raffles, and other games of chance (collectively, “raffles” for purposes of this guidance).
 - 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.
- **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.

INCENTIVES AND COMPENSATION

The incentive must not be viewed as a way of offsetting risks or considered 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. 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. All information concerning incentives should be stated in the consent document, including the amount, method, and timing of disbursement.

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. 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 with the incentive accruing as the study progresses (e.g., for multiple sessions or studies of considerable duration).

The nature, value, and method of payment should consider the context of the local economy, cultural practices, living conditions, and opportunities for earnings. These considerations apply to research conducted both inside and outside the United States. Participants that are **children** may receive incentives. The amount and method of payment should be age appropriate. If course credit or extra credit is offered to a student population, the researcher must offer a nonresearch activity that is equivalent in effort and time/duration to research participation. For incentives involving **prisoners**, specific prison restrictions and requirements should be considered.

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. The UWG IRB may or may not approve a **recruitment bonus**, or incentive for study staff to recruit subjects or to subjects for recruiting other subjects. Researchers proposing monetary-value incentives, including cash, gift cards, gift items, and checks, for studies supported by University funds should refer to University policies for guidance on payments. Studies supported by external grants must follow the grant guidelines for all incentives and compensation. 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.

THE USE OF DRAWINGS OR RAFFLES

The definition of a drawing is broad and includes any procedure in which a prize is given away, as long as the participant is required to provide something of value (i.e., "consideration") in exchange for the chance to win. Consideration can be the purchase of a raffle ticket or the giving of an individual's time to participate in a research study. In the research context, the IRB may permit the incentive scheme to allow a drawing (lottery or raffle) if any person in the general public is allowed to enter the drawing in order for the raffle to satisfy state laws. This means the general public must be allowed to enter the drawing without being required to participate in the research as a precondition of entering. Otherwise, it is a felony in Georgia to conduct a lottery, raffle, or similar game of chance without obtaining a license ([O.C.G.A. § 16-12-22.1](#))

When a raffle may be conducive to a research study, the UWG IRB will review and approve the raffle procedures as part of the protocol review and approval process. The IRB may consult with UWG Legal Counsel regarding the legality of any planned raffle. Note that, because of the requirements of Georgia law, confidentiality of raffle winners cannot be promised by the researcher.

GUIDANCE FOR RESEARCHERS

The researcher must fully describe the incentive amount and disbursement plan in the IRB submission. The researcher is responsible for the accountability of funds received and disbursed to research participants, including departmental requirements and reporting to university business departments to fulfill federal and University policies and requirements. The researcher is responsible for informing the participants in the consent process of the information needed from them in order to receive the



incentive, as well as describing how the obtained information will be stored, used, and who will have access to it.

If a researcher wishes to utilize a drawing to encourage participation in research, he/she must adhere to the following provisions and explain the drawing procedures in the IRB application and, as applicable, in the Informed Consent document(s) or Information Sheet(s):

- The research may not include activities that are More than Minimal Risk (i.e., the protocol must be reviewed in the “exempt” or “expedited review” categories).
- The raffle must be open to all individuals, whether they participate in the research or not. The researcher must provide the IRB with a comprehensive plan for how the public will learn of the research study, how the public may participate in the raffle, how the prize will be selected (i.e., date and time of the drawing, person who will conduct the drawing, etc.), how the recipient will be notified, how persons involved in the raffle may ultimately discover who received a prize, and other relevant information pertaining to the raffle.
- All persons who elect to participate in the raffle must have the same chance of winning the prize(s). The researcher must include statements that entry into the raffle is not contingent on participation in the research and that a person may remain eligible for the raffle even if he/she withdraws from a study or does not complete every question.
- Any raffle should only be open to those eighteen (18) years of age and older and who reside within the United States.
- The raffle must be conducted in a manner that does not compromise participant anonymity or confidentiality that is protected by other protocol methodology.
- The researcher must provide the IRB with information concerning the amounts and number of prizes involved in the raffle. Both the amounts and number of prizes must not be coercive or exert an undue influence on participants, and the disparity between subjects should be considered (i.e., it is preferable to have several lower value prizes than one higher prize because the disparity between subjects is reduced).
- The researcher, any co-researchers or research assistants named in the protocol, immediate family members (spouse, parents, siblings, and children) of such persons, and any other persons with a direct interest in the research study must be excluded from participation in the raffle.
- The researcher must maintain records regarding the raffle along with other research-related documents.

IRB PROCEDURES

An IRB Staff Member will review the submission to determine the appropriateness of the proposed incentive according to the above guidance.

- For non-committee reviews, the IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.
- For committee reviews, the IRB committee will document missing information or required modifications in the meeting minutes and in post-meeting correspondence.

Proposed incentive amounts and plans for disbursement that are not compliant with this guidance can be discussed with the Director of Research Compliance or IRB Chair and, for funded research, the



Director of the Office of Research & Sponsored Projects. The following are examples of issues that may need to be adjudicated:

- A large bonus for the last visit or to influence retention
- Finder's fees, bonus payments, or incentives for study staff to recruit subjects or to subjects for recruiting other subjects

The ***Designated/Regulatory Reviewer*** will document determinations that the requirements of this guidance 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.

Please contact the UWG IRB at irb@westga.edu if you have any questions.