

<u>Scope</u>: This document is intended to guide researchers in the design of their protocol so that their research satisfies regulatory requirements and adheres to best practices related to compensating human research subjects. This document also includes instructions meant to help researchers ensure they provide sufficient information in the protocol materials about compensation for the Institutional Review Board (IRB) to determine whether or not the compensation is appropriate.

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I. General Considerations

Federal regulations require that researchers minimize the possibility of <u>coercion</u> or <u>undue</u> <u>influence</u> in the process of recruiting and consenting research subjects (45 CFR 46.116). These must be avoided when compensating subjects for their participation in research.

Compensation refers to anything given to subjects as remuneration for the time and inconvenience of participation in research. Compensation can be monetary or non-monetary, and can be offered in a range of forms, including but not limited to cash, gift cards, vouchers, trinkets, course credit, and the opportunity to enter a drawing for a prize. Compensation is distinct from participant reimbursement, whereby researchers pay some or all of the subjects' costs for participation - e.g. transportation, parking, lodging, etc.

For all research, the method and value of compensation must be appropriate for the subject population and the research activities. What constitutes "appropriate" compensation for any study is determined by consideration of the research activities, subject population, and the cultural/social/political context in which the research will take place. In other words, some forms, amounts and methods of compensation may be appropriate for some individuals or groups, but not others

Compensation cannot be so great that it entices participants to engage in any activity to which they are averse, or to act against their better judgement. The following regulatory requirements and ethical principles must be considered when developing a compensation plan associated with any research protocol.

 Researchers must avoid coercion and undue influence. The following definitions have been adapted from the federal Office for Human Resource Protections (OHRP) guidance on minimizing the possibility of coercion or undue influence:



- Coercion. Compensation is considered coercive if it entails an overt or implicit threat of harm/negative consequence which could compel involuntary participation and/or compliance. For example, telling a prospective subject she will lose access to needed services if she does not participate in the research is coercive and would not be permitted.
- O Undue influence. Compensation that includes an excessive or inappropriate reward or other overture may constitute undue influence. For example, offering college students \$100 each to complete a 20 minute survey on illegal drug and alcohol use could be viewed as unduly influential because the amount could entice students to disclose information that they would not otherwise willfully disclose to strangers.
- When possible, investigators should pro-rate compensation in other words, offer partial compensation for partial or incomplete participation in specific study activities or the study as a whole. Making receipt of compensation contingent upon completion of all study activities may constitute coercion or undue influence.
- Subjects participating in the same study and completing the same tasks should be
 compensated equitably. Variation in compensation is acceptable when it can be justified
 for example, it is reasonable that compensation for subject populations in different
 countries may vary according to cultural customs.
- Because providing compensation may require the use of personally identifiable
 information from email addresses used to email gift cards, to Social Security Numbers
 required for tax reporting purposes the mechanics of compensating participants can
 contribute to risks associated with a loss of privacy or breach of confidentiality.
 Researchers should develop mechanisms for compensating subjects that reduces the
 exposure to these risks.
- In some cases, offering participants money or items of value may increase risk of harm to them. For example, giving cash to prisoners or smartphones to members of communities where that technology is largely unaffordable may increase the likelihood that the participants could become targets of theft or violence. Researchers must consider and take measures to prevent or mitigate the potential for such risks when developing a compensation plan.
- Compensation should be presented in the same manner as other information in the recruitment and consent materials. Presentation of compensation must not detract from important information participants need to consider in order to fully understand the study and assess the risks associated with participation.
- Compensation is not considered a benefit of research participation and must not be discussed as such.

II. Instructions for Incorporating Compensation into Protocol Materials

The IRB must determine whether or not the proposed compensation does in fact promote voluntary participation, is equitable, and does not present unnecessary or unacceptable risk of harm/negative consequences to participants. To make this determination, the IRB needs details about what, when, and how compensation will be provided. Additionally, the IRB needs to see how this information will be conveyed to participants during the recruitment and consent processes. This section



explains what information must be provided in the Research Plan, as well as guidance for the development of the recruitment and consent processes.

A. The Research Plan

1. Section D - Research Population and Recruitment Methods

- Describe the amount/value and method of the payment (i.e., cash, gift card, course credit, etc.), and how and when compensation will be provided.
- Explain why compensation is being provided as well as why the amount being offered is appropriate for (1) the subject population; (2) what is being asked of the participants; and (3) the cultural/social/political context of the research.
- Explain whether or not partial compensation will be offered in other words, will participants who complete only some tasks or terminate participation prior to study completion receive any compensation at all, if so, how much?
- It may be appropriate to reimburse participants if they are asked to incur costs (e.g., parking). If participants are asked to incur costs, the extent and nature of these costs must be clearly stated. If they will be reimbursed for some or all of these costs, the details of reimbursement should be explained, and in a way that differentiates the reimbursement from other forms of compensation (e.g., compensation for task completion, bonuses for study completion, extra credit, etc.).
- If compensation is in the form of course credit or extra credit, describe the alternative activities available for students not participating in the research.
- Compensation may take the form of a chance to win money or a prize in a "drawing" (e.g. a drawing for a \$20 UO Duck Store gift card). Given that the terms "lottery" and "raffle" have specific meaning under state laws that typically do not apply to compensation for participation in research, researchers should use the term "drawing" in the protocol, recruitment, and consent materials. Additionally, a person's chances of winning the drawing should be conveyed to the participant.

2. Section F- Provisions for Subject Privacy and Data Confidentiality

- What personally identifiable information will be used to provide the compensation, and how that information will be stored and secured; who has access to it; and when it will be destroyed.
- When applicable, retention of identifiable information for compliance with the UO's Business Affairs Office's (BAO) policy should also be explained. See section below for additional information.

B. Recruitment Materials

• The recruitment materials may include information that compensation will be provided; however, information regarding compensation should not detract from important information participants need to consider in order to fully understand the study.

C. Consent Materials

The consent materials must contain the following information:

• The amount/value and method of the payment (i.e., cash, gift card, course credit, etc.), and how and when compensation will be provided.



- Whether or not partial compensation will be offered, and if so, how much.
- If participants will be reimbursed for some or all of any costs associated with participation in the research, the details of reimbursement should be explained, and in a way that differentiates the reimbursement from other forms of compensation that may be offered.
- If compensation is a chance to win money or a prize in a "drawing" (e.g. a drawing for a \$20 UO Duck Store gift card), the person's chances of winning should be conveyed.
- See <u>UO's BAO Policy on Payments to Participants</u> and include the applicable suggested consent language regarding taxable income reporting requirements.

III. Vulnerable Populations

Below are some general guidelines for and examples of compensation considerations for certain vulnerable populations, as well as examples of forms or methods of compensation that should be avoided.

A. Minors

In the U.S. "minor" typically refers to youth under the age of 18, but the age at which youth can legally provide consent does vary across jurisdictions. It is generally acceptable to compensate youth (and/or their parents) for their participation in research. When conducting research with minors, researchers should consider the following:

- Because parents have the authority to grant permission for their children to participate in research, compensation may entice a parent to allow their child to participate against the parent's better judgment, and/or pressure their child to participate in the research. Often, researchers can avoid undue influence of and by the parents by reimbursing them for expenses associated with their child's research (e.g. transportation to the lab), and offering the child a token of appreciation at the end of the study.
- Compensation must be appropriate for the age and/or developmental stage, and context of the study. For example, a small toy may be appropriate for a young child, while a gift card may be more appropriate for a teenager. Offering cash to youth should be approached with sensitivity to matters such as how the child might view the value of the cash, and whether or not the child's possession of the cash could put them at risk of harm.
- Consideration of allergies, health hazards, and food handling requirements must be made when offering candy or other forms of food.
- Youth are particularly susceptible to peer pressure. Researchers should design their study and the offer of compensation so that peer pressure to participate or "get what others are getting" is minimized.

B. Prisoners

The terms of any individuals' incarceration and/or the site of their incarceration may restrict the amount, form, and method of compensation that is permissible. Researchers must check with the relevant penal institution/authorities about restrictions on compensation prior to developing their protocol and plan for compensation. Additionally, federal regulations recognize that prisoners experience constraints that may affect their ability to make a truly voluntary decision about participation in research and implore IRBs to ensure proposed



research is not coercive. The following must be taken into account when proposing compensation for prisoners:

- The amount and method of compensation for participation must be made with consideration of the payment structure within the facility.
- When possible, the offer of compensation should be conveyed privately to individuals to help promote the safety of participants.
- Participation in research cannot be induced with promises of additional institutional privileges.

C. Low income and other socially/materially vulnerable populations

Creating opportunities for all members of society to participate in research is a matter of justice. As already discussed, however, compensation should not be so great that it obfuscates the true risks, costs and benefits of participation, or entices participants to engage in activities to which they would be averse or would otherwise find objectionable. Compensation should be tailored to the resources and vulnerabilities of the population. The following considerations must be made:

- The method of compensation must be appropriate for the participants' circumstances, which could include no or limited access to email, bank accounts, particular retailers, etc. For example, a gift card to a grocery store serving the neighborhood where participants reside may be more appropriate than an Amazon gift card.
- When low income status intersects with other material or social vulnerabilities, such as homelessness, chronic illness, or minority social status, special care must be given to simultaneously avoid either exploiting potential participants by virtue of under payment, or unduly influencing them by offering excessive compensation. Individuals or organizations who work with those populations may be able to provide guidance on what amount, form and method of compensation is appropriate.

D. Undocumented Populations

Researchers who include individuals who lack legal status must be aware that the gathering of individually identifiable information and tracking the compensation may put these individuals at greater risk. These risks must be mitigated to the greatest extent possible, which may necessitate offering something other than monetary remuneration.

IV. UO's BAO Policy on Payments to Participants

The university has legal and fiduciary responsibilities to properly account for all payments made to individuals, be they employees, students, vendors, or research subjects. Responsibility for financial management of human subject research rests with the departmental accounting office (as account custodian) with oversight by the Principal Investigator (PI). Individuals in these roles should clearly understand the financial authority and institutional obligations as outlined in the UO Business Affairs Office procedures (pdf).

The UO BAO procedures follow a tiered structure used to determine the appropriate level of information collected which may result in the tracking of a participant's personally identifiable information. For questions regarding types of payments, payment procedures and tracking requirements, researchers and department administrators should contact <u>UO Business Affairs</u> Office.



Researchers need to be mindful of the tracking requirements and consider any risks compensating participants may introduce as a result. Researchers need to ensure participants in research are informed that:

- Internal Revenue Service (IRS) considers payments for participation in research studies to be taxable income to the recipient; and
- When applicable, personally identifiable information may need to be given to the department depending on amount and method of payment.

The table below provides <u>suggested language</u> to include in the informed consent process and, if applicable, in the informed consent form based on the tiered structure for tracking of payments. Please work with Research Compliance Services if the language below needs to be adapted to be compatible with your research design.

BAO Threshold for Individual Subject(s)	BAO Tracking Requirements	Suggested Informed Consent Language
\$100 or less	None	Please be aware, compensation for participation in research studies may be considered taxable income.
\$100.01-\$599.99	Informal tracking at department level	Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data and accessible by UO administrators. If you receive \$600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.
\$600 or greater	Subject needs to complete applicable IRS Form(s) for annual tax reporting	Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. Because you will receive \$600 or more in a calendar year, you will be asked to provide additional (e.g. Social Security Number) information for tax reporting purposes. This information is stored confidentially and separate from research data.

Note: The IRS rules differ for non-resident aliens and include additional requirements for payments totaling \$100.01 or above; contact BAO for additional information.



V. References and Additional Resources

A. References to sources of information used in creation of this document

- U.S. Department of Health and Human Services (DHHS) Code of Federal Regulations Title 45, Part 46 Protection of Human Subjects: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- U.S. Food and Drug Administration (FDA) Code of Federal Regulations Title 21, Part 50 Protection of Human Subjects (other parts, e.g. parts 56, 312 and 812, also apply): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
- DHHS's Office for Human Research Protections (OHRP) FAQs on informed consent, including:
 - o What does it mean to minimize the possibility of coercion or undue influence: http://www.hhs.gov/ohrp/policy/faq/informed-consent/what-does-coercion-or-undue-influence-mean.html
 - o When does compensating subjects undermine informed consent or parental permission: http://www.hhs.gov/ohrp/policy/faq/informed-consent/when-does-compensating-subjects-undermine-informed-consent.html
 - What constitutes coercion or undue influence when students are involved in research in a college or university setting: http://www.hhs.gov/ohrp/policy/faq/informed-consent/what-constitutes-coercion-when-students-are-involved.html
 - o Can non-financial enrollment incentives constitute undue influence: http://www.hhs.gov/ohrp/policy/faq/informed-consent/can-non-financial-enrollment-incentives-constitute-undue-influence.html
- IRS Miscellaneous Income
- UO BAO policy on compensation of research subjects.
- Grant & Sugarman (2004). Ethics in Human Subjects Research: Do Incentives Matter? Journal of Medicine and Philosophy, 29 (6): 717-738.
- Dickert & Grady, (1999). What's the price of a research subject? Approaches to payment for research participation. *The New England Journal of Medicine, 341*, 198-203.

B. Additional resources

• Bryman, Alan. Social Research Methods (2012).