



Procedure Title: Human Subject Payments

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	3/31/2017	Executive Lead:	Chief Research Officer
Effective:	3/31/2017	Revision History:	.01- 05/01/2017; .02 – 06/26/2018; .03 – 10/01/2019; .04 – 06/28/2021; .04 – 3/3/2023
Approved by:	Institutional Review Board		
Procedure Number:	106.05		
Key Words:	Incentive, Payment, Remuneration, Lotteries, Certificate of Confidentiality		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding remuneration in order to obtain sufficient human subject participation in research.

This SOP must be used as a guide in parallel with OSA Policy 1.0 to comply with proper reimbursement of human subject compensation. SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

General Information:

Compensation to subjects participating in research is often given in order to obtain sufficient participation. Subjects should be paid enough to make up for their time and trouble, but not so much that their decision to volunteer or continue in a study is influenced by the value of the compensation being offered. The amount of compensation should also be based on a reasonable consideration of the duration of time spent in research activities including but not limited to preparation, participation, recovery, follow-up activities and the amount of effort expended. Additional consideration should be given to ensure that no one participant population is given more burden or risk than other populations. Compensation may include cash, checks, gift cards, pre-paid debit cards, extra credit, and other non-monetary items.

The IRS treats compensation to research participants as taxable income to both U.S. residents and non-residents. The tax treatment depends on the recipient's tax status, residency status and the amount paid. Payments aggregating \$600 or more to U.S. residents during a calendar year require PNWU to issue a 1099-MISC to the participant. This is true whether the incentive is cash, pre-paid debit cards, check, gift card, or small value items.

Note: Only research projects are able to utilize gift cards for incentives.

All research compensation issued to PNWU employees or student employees, regardless of the amount issued, will be reported as income on the employee's annual Wage and Tax Statement Form (W2).

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Reviewing compensation timelines and amounts to ensure:
 - appropriate levels and timing of remuneration
 - amounts of remuneration are not coercive to participant in research;
 - relevant federal, state, and local regulations;
 - other applicable guidance;
- Obtaining input from investigators
- Evaluating undue influence to participants

The Office of Scholarly Activity (OSA) is responsible for:

- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community;
- Communicating with the Office of Finance due to the fact payments to research participants can have income tax implications

The Office of Finance is responsible for:

- Supporting the OSA, the IRB, and investigators
- Meeting requirements set forth by the Internal Revenue Service (IRS)
- Proper documentation needed for A-133 audits

The Investigator is responsible for:

- Completing the educational training in human subject research protection
- Maintaining continuing knowledge of, and comply with, the following:
 - relevant ethical principles;
 - relevant federal, state, and local regulations;
 - other applicable guidance;
- Advocating a culture of human subject protections at PNWU via educational training in human subject research protection

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Human Subject
- Investigator
- Federal Wide Assurance
- Compensation
- Incentive
- Reimbursement
- Remuneration
- Research Payment

Procedures:

1. When conducting human subject research, the protocol must be submitted to and approved by the Institutional Review Board and informed consent of participants must be sought and documented.

2. First and foremost, subject payment may raise ethical issues around voluntary participation and the individual's need to make informed choices about research that are based on the real risks and benefits of participation, not on financial incentives.
3. Federal regulations and commentaries offer guidance about such remuneration, but set no strict limits, leaving the IRB to decide how much payment is too much or not enough based on what the "payment" is (e.g., money, gift cards, extra credit, etc.) and the nature of the task (simple survey, manipulation with deception, etc.) that the participant is asked to perform.
4. Your application form submitted to the IRB should indicate and justify proposed levels and purposes of remuneration, which also should be clearly stated in the accompanying consent forms.
5. The Food and Drug Administration cautions against payments that "...represent undue influence." The National Institutes of Health similarly warns IRBs about payments that cause "undue inducement." Following these general cautions and based on its own experience, the IRB will provide the final determination about subject payment.
6. When subjects are reimbursed for actual costs resulting from their participation in research that is generally not considered remuneration. Subjects' reimbursement for actual out-of-pocket expenses associated with research participation such as meals, parking, travel, and lodging is common and typically receipts are requested. It is sometimes difficult to determine whether the payment is a remuneration or reimbursement. Therefore, the consent form must clearly outline and define the process.
7. The use of incentives from an externally funded sponsored project for participants must be described in the grant proposal. If the incentives were not described in the grant proposal, the purchase of incentives on a sponsored project requires prior written approval from the sponsor. If prior approval is not obtained, the incentive purchase is not allowable on the grant.
8. Incentives must be purchased through the Office of Scholarly Activity, the Principal Investigator (PI) will need to provide the following information to OSA:
 - a. The project name (or funding/grant ID) to be used to purchase the incentives.
 - b. Name of the incentive vendor
 - c. Value of incentive
 - d. Number of incentives needed (If gift card, these are ordered in batches in order to avoid having leftover, unusable cards which typically cannot be returned)
 - e. Participant demographics including name, address, telephone number, email address and whether the participant is a student or employee of the university, and date of participation. In instances where the incentive exceeds the thresholds described below, the investigator will need to collect a W9 for each participant who receives an incentive and provide those W9's to OSA. Electronic collection of W9's is preferred.
 - f. Contact the OSA to set up a REDCap project to track your incentives. The REDCap form is part of the study data collection instruments that must be submitted to the IRB with the application for review and approval.
9. If this is not a confidential study document:
 - a. The name, date, and incentive number of each research participant receiving an incentive must be documented.
 - b. When issuing incentives via a physical gift card or check, a sign-off from the participant who received the incentive must be documented.

- c. Maintain this documentation in case your grant is audited, for as many years as the federal or state government document retention policy states.
- 10. If this is a confidential study (e.g covered by a [certificate of confidentiality](#)) document:
 - a. Provide a list of incentive reference numbers instead of the participant names (example FD0001, FD0002, etc.) and the dates the incentives were distributed.
 - b. These reference numbers should refer back to documentation the PI maintains which holds the participants' true identity, a sign-off from the participant who received the incentive, or an e-mail acknowledging they received the incentive if sent by mail, email, and any other support for the study.
 - c. Maintain this documentation in case your grant is audited, for as many years as the federal or state government document retention policy states.
 - d. Document IRB approved waivers of signed consent according to 45 CFR 46.117(c)(1) (i.e. that the consent form is the only record linking the subject to the research and the principal risk would be potential harm resulting from a breach of confidentiality).
- 11. Non-resident alien participant protocols will be reviewed on a protocol by protocol basis with the best interest of human research protections applied.

Finance Information and Procedures:

- 1. Each investigator, per study, must document payments issued to research participants. It is necessary to document payments and collect demographic data in order to create an audit trail for investigators and finance, as well as, allow finance to issue a 1099-MISC form to participants when IRS reporting limits (\$600 annually) are reached. Compensation issued to PNWU employees or student employees is income, regardless of the amount issued, and will be reported on the employees annual W-2 (Wage and Tax Statement Form). Investigators are required to work with OSA to track research payments. Electronic tracking is required in REDCap to enable OSA to report all incentive payments at the end of the calendar year.
- 2. Compensation to research subjects:
 - a. Compensation to non-student recipients of \$100 or less can be made by cash, pre-paid debit cards, gift card, or gift in kind (e.g., books, t-shirts, food). The study team is required to collect date of participation, amount issued, type of incentive, participant name, address, telephone number, email address, and whether or not the participant is a student or employee of the university.
 - b. Student compensation of \$25 or less can be made by cash, pre-paid debit cards, gift card, or gift in kind. Collect date of participation, amount issued, type of incentive, participant name, address, telephone number, email address, and whether or not the participant is a student of the university.
 - c. Payments to foreign nationals or non-resident aliens will be handled on a case by case basis.
 - d. If the payment is more than \$100 for an employee or community participant OR more than \$25 for a student participant, a W-9 must be completed by the recipient. The W-9s and amount of compensation must be provided to Accounts Payable by the Office of Scholarly Activity no later than December 15th each year.
 - e. If the combined total compensation to an individual is \$600 or more in a calendar year PNWU Finance will issue a 1099-MISC.
- 3. Lotteries and "Random Awards" as Incentives for Research Participation Researchers with limited funds for compensating participants often ask whether they can offer a random drawing for monetary or other awards as incentive for enrolling or continuing in their study. According to PNWU,

such random drawings (whether physical or virtual) in research projects constitute a lottery under various state laws in PNWUs catchment area, and the state “prohibits any person in the state to conduct any lottery drawing for the distribution of a prize or prizes by lot or chance, or advertise any such lottery scheme or device.” Although certain charitable and nonprofit organizations may conduct lotteries, even they may not “require an entry fee, donation, substantial consideration, payment, proof of purchase, or contribution as a condition of entering the drawing or of being selected to win a prize.” Therefore, PNWU has determined that a random drawing cannot be used as incentive to enroll research subjects or to continue their participation, which would be a “substantial consideration” for entering the “drawing.”

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
3. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf>)
4. Code of Federal Regulations, Title 45, Public Welfare, Department Of Health And Human Services Part 46, Protection Of Human Subjects, Revised January 15, 2009, Effective July 14, 2009. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>
5. Department of Health and Human Services (HHS), Attachment A – Addressing Ethical Concerns Offers of Payment to Research Participants. <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html>
6. Washington State Legislature General Lottery Rules. <http://apps.leg.wa.gov/WAC/default.aspx?cite=315-06&full=true>
7. Internal Revenue Service Form W-9. <https://www.irs.gov/pub/irs-pdf/fw9.pdf>
8. Internal Revenue Service Instructions for Form W-9. <https://www.irs.gov/pub/irs-pdf/iw9.pdf>
9. Internal Revenue Service Certificate of Foreign Status of Beneficial Owner for United States Tax Withholding and Reporting (Individuals)[Form W-8BEN] <https://www.irs.gov/pub/irs-pdf/fw8ben.pdf>
10. Internal Revenue Service Instructions for Form W-8BEN. <https://www.irs.gov/pub/irs-pdf/iw8ben.pdf>
11. Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5728432/>
12. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
13. PNWU Gambling Policy

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00/3-31-2017	M. McCarroll	New Standard Operating Procedure
.01/ 5-1-2017	M. McCarroll	Changes per HRP Consultants. Add bullet 3.1 reevaluating undue influence; 3.2 changed "gift cards" to incentives throughout SOP; 4.1 added reference to OSA Policy 1.0; Added 7.5 Reference to Incentive Tracking Form.

.02 / 6-26-2018	M. McCarroll	Added 6.17 and minor formatting changes
.03 / 10-01-2019	C. Case	Put into the new PNWU SOP Format
.04 / 07-22-2021	C. Case	Added general information section on page 1; #8 revised to remove the research email address and adding the OSA email address; #9 deleted and added as items a-d under #8; and renumbered: #13 revised to add a statement about incentives to employees and that they will be included in the annual W2 form; #13 revised with the addition of a statement that all incentives issued to employees/student employees is considered income and will be reported on the annual W2 issued to the employee. #14 added new item with specific information about compensation, compensation limits and tax reporting information; Added additional references to reference section at the end of the SOP
.05 / 3-6-2023	C. Case	Minor revision to combine items 2 & 12 into a new #2 and added a heading for the finance procedures. Revised #8 in procedures to include information to be collected for incentives and instructions for the investigator to contact OSA to set up a REDCap project to collect incentive information.

Appendices:

None