PARTICIPANT COMPENSATION: ETHICAL AND PRACTICAL CONSIDERATIONS

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WHAT KINDS OF STUDIES USE PARTICIPANT PAYMENTS?

- Clinical
- Clinical trials
- Basic science
- Social sciences
- Behavioral sciences
- Marketing
- Education research

If the research involves humans who are not working for the project, you may well have participant payments.
AGENDA

- Ethical Considerations
  What are the challenges in deciding appropriate compensation?

- Practical Considerations
  What do you need to consider before paying participants at Ohio State?
Designing a fair payment model

- Amount
- Participants
- Mode
- Participant burden

https://www.sciencenews.org/article/culture-shapes-sense-fairness
WHY DO WE PAY PARTICIPANTS?

In studies that asked about motives to participate, 60%-90% of subjects in studies with little or no direct benefit reported that payment influenced their decision.

• Clearly, participant compensation helps with recruitment.
• Compensation may also enhance compliance with the research protocol.
WHAT DO WE PAY PARTICIPANTS?

When possible, we want to acknowledge the time spent and trouble experienced by participants.

- Compensation for time
- Reimbursement for out-of-pocket expenses (parking, travel)
- Compensation for taking on risks by participating in research
- Compensation for following the protocol – making extra efforts, performing actions that they wouldn’t otherwise do
HOW MUCH IS FAIR?

- Reimbursement
- Hourly wage
- Market rate (higher pay for high risk or low benefit studies)
- Fair share (fixed proportion of the per-subject reimbursement to the investigators)
- Are some parts of the study harder than others?
The trick is this:
To balance paying your participants reasonable compensation against unduly influencing them.
You are considering enrolling in a study of a new kind of eye drop. The second visit, which will take 3 hours, includes a comprehensive eye exam, and it takes place on campus. The doctor will put an eye drop in your eye, and you are warned it will sting for about 3 minutes. After sitting in the dark for 15 minutes, the doctor will use an instrument that touches your eye while it is numbed. After the visit, you will need to wear sunglasses for an hour to protect your eyes from having them dilated for the exam.

How much is fair compensation for you for this visit? You are offered a parking pass.

- A. $20
- B. $50
- C. $75
- D. You couldn’t pay me enough to have someone stick something on my eye
WHAT PAYMENT SCHEDULE IS FAIR?

• How often do you see your participants?
• How often do they submit something, like a survey?
• Is the study over in a week? A year? Four years?
STUDY POPULATION CHARACTERISTICS

MATTER

- Culture
- Financial status
- Educational attainment
- Age
- Disability status
- Citizenship status
- Developmental status
- Housing status
- Pregnancy
- Prisoners
- Students
- Employees
- Legal issues
- Family members
REGARDLESS OF AMOUNT...

- Pay participants comparable rates/amounts
- Compensation should not entice people to accept risk that they wouldn’t ordinarily accept
- Prorate payments to match participation, even for drop outs
- Pay within a reasonable time frame relative to participation
INCENTIVES THAT ARE OFTEN ACCEPTABLE

- Cash, checks
- Gift cards, money on BuckID
- Merchandise
- Class credit
- Community service points
- Drawings, so long as all participants (including withdrawals) are eligible
Your new study investigates some side effects of Celebrex. The company is funding the study and has sent you branded thumb drives for the participants. Is this an appropriate incentive?

A. Yes, it’s ok
B. No, it’s inappropriate
WHAT DO YOU THINK?

- Your new study investigates some side effects of Celebrex. The company is funding the study and has sent you branded thumb drives for the participants. Is this an appropriate incentive?

A. Yes, it’s ok
B. No, it’s inappropriate
You are studying a particular social effect on a population of people distrustful of authority figures, and you anticipate recruitment difficulties. You are in touch with a trusted community leader. Which of the following is inappropriate?

A. You ask the leader for help recruiting and pay her a small fee for each person directed to the study
B. The leader agrees to help you recruit on the condition that you volunteer at community functions while providing your study information
C. You hire the leader as a consultant for 10 hours of their advice and help designing your recruitment materials
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INFORMED CONSENT

- People have the right to know about planned study compensation
- Compensation and participant burden must be clearly explained in the informed consent process (e.g., script, document)

The Ohio State University Consent to Participate in Research

<table>
<thead>
<tr>
<th>Study Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher:</td>
</tr>
<tr>
<td>Sponsor:</td>
</tr>
</tbody>
</table>

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose:

Procedures/Tasks:

Duration:

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.
Payments to non-resident aliens (NRAs) can lead to problems for the participant

- *Any payment* is taxable income
- If you are paying >$100 to a participant for one protocol during one calendar year, special rules for non-resident aliens (NRAs) apply
- There are forms that both the study team and the participant complete for payments >$100
OUR RESPONSIBILITY TO VULNERABLE PARTICIPANTS

- Protect the dignity of vulnerable participants (e.g., due to age, housing status, disability)
- To the extent possible:
  - Specify to whom payments will be made
  - Design payments so that they are made to the actual participant
  - Obtain participant’s signature on receipt
  - Transparency
BANKING STATUS MATTERS

Banking Status in the USA

What can we do for those who don’t use a bank, or are financially insecure?
SCENARIO: ROLL ‘EM!

Your fate with the cast of a die
<table>
<thead>
<tr>
<th>Participants</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;18</td>
<td>Disabled</td>
<td>Impoverished</td>
<td>Non-resident Alien</td>
<td>15-60 years</td>
<td>Adults only</td>
</tr>
<tr>
<td>Amount per year</td>
<td>$10</td>
<td>$100</td>
<td>$200</td>
<td>$500</td>
<td>Trinket</td>
<td>40” TV</td>
</tr>
<tr>
<td>Mode of interaction</td>
<td>In their home</td>
<td>Phone</td>
<td>Online</td>
<td>Text</td>
<td>Mail</td>
<td>In person at OSU</td>
</tr>
<tr>
<td>Burden</td>
<td>2x week for 2 months</td>
<td>1x year for 3 years</td>
<td>1x week for a year</td>
<td>5x day for a week</td>
<td>At will</td>
<td>Just once</td>
</tr>
</tbody>
</table>
PRACTICALITIES

- Your Procedures
- Source of Funds
- Taxes and Citizenship
- Documentation and Monitoring
CONSIDERATION 1: YOUR PROCEDURES

- Who is allowed to get and handle petty cash?
- How do you ensure that all forms of payment are used for the study for which they are intended (monitoring)?
- Do you have separation of duties (custodians and monitors)?
- Do you have secure storage?
- How do you ensure similar forms of payment for multiple studies are not co-mingled?
- What do you do when a custodian leaves Ohio State?
Office of Sponsored Programs (OSP) funds
- More leeway on payment amount permitted per year
- Sponsor requirements may dictate options
- No leeway in what study you can use the payments for
- Petty cash monitoring provided
CONSIDERATION 2: SOURCE OF FUNDING

University funds
- Start-up funding, internal grants, other internal accounts
- >$100/participant/protocol/year? A/P!
- Department responsible for monitoring program
- Department expectations vary
CONSIDERATION 3: TAXES AND CITIZENSHIP

- All payments in cash or in kind are **taxable income**
- OSU funding: >$100/protocol/year -> payments reported to IRS (A/P)
- OSP funding: >$500/protocol/year -> payments reported to IRS

- **Participants’ legal status matters**
  - Citizens and permanent residents: taxation is the main consideration
  - Non-resident aliens: does their visa allow them to be paid?
    - Up to $100/protocol/year is ok
    - More than $100/protocol/year: OSU/OSP needs to verify that the participant is allowed to be paid that much BEFORE THEY ARE ENROLLED IN THE STUDY
Before enrolling a non-resident alien participant, determine if they can be paid

Obtain Vendor Setup form, paper copy of passport, and visa
  · If A/P assigns a vendor ID, you can proceed

Get the Nonresident Alien Payment Request form and, if applicable, Compliance Form for Payments to B or W Visa Holders to request payment
  · NRA will need to complete GLACIER forms, or Ohio State will withhold 30% of the payment for taxes
CONSIDERATION 3: CHOOSING THE BEST PAYMENT TYPE

Ethical concerns

Security concerns (for person and for funds)

Anonymity of participant

Amount of payment per participant per protocol per calendar year

Citizenship status

Is funding source OSP or OSU?

Does your department allow payment method?
PAYMENT OPTIONS

- Petty cash
- Check from Accounts Payable
- OSP project checking account
- Gift cards
- ClinCard
- Parking passes
- Non-cash compensation
- Others

Do you know your department’s expectations?
PETTY CASH OVERVIEW

- Remember: the money is not expensed until it is paid to a participant and that person signs a receipt
- Keep receipts with study records
- Provide a log (de-identified) to OSP (or your department, if not OSP) to prove appropriate expenditure
- Return any unspent funds at end of study
THE ADVENTURES OF CHRIS MCSTUDY
OR GETTING PETTY CASH

PR-HS1: PI, chair sign

You may only have cash on hand equaling the amount on this form

Attach to eRequest

Cash check

Pay HS & get receipts

Need more $? Create log of participants paid. Attach to eRequest. Request $ value reported on log.

This is called a replenishment

Need more cash on hand? Do another PR-HS1 to increase
ACCOUNTS PAYABLE

- A/P required in some cases
- Non-resident aliens >$100/protocol/year
- OSP funds: >$500/protocol/year
- Ohio State funds: >$100/protocol/year
- Need a Vendor Setup form for each individual
- Get the vendor ID before doing your eRequest so that you can keep participant’s name out of eRequest
- No receipt needed!
- This is a slow payment method
CHECKS FROM OSP PROJECT FUNDS

- Work through the Treasurer
- Complete PR-HS1 form
- Cost of checks is charged to account
- OSP transfers money to the checking account
- Limits to non-citizen/non-permanent residents pertain – not a replacement for A/P checks
- No receipt needed
- Not allowable for university funds
GIFT CARDS

- Cash equivalents
- Purchase like any other item
  - OSP: limited to $100/participant/protocol/year
- Keep receipts with study records
- Unused cards purchased on OSP funds at end of study
  - Department must buy cards from project
- Sponsor-provided cards
- Best practice: department monitors usage
CLINCARD

- Reloadable gift cards
- Charge for each new card and to reload
- Contact Jeff Kemper at OSP to set up
  - OSP only
- Vendor Setup form needed for each participant
  - <$500/participant/year? Partially completed form only
- Participants sign receipt when receiving new card
- Internal Audit requires departmental monitoring
  - Compare usage log to PI Portal
OTHER NON-CASH COMPENSATION

- T-shirts, key chains, stuffed animals...
- Advertising or participant compensation?
- OSP will likely need justification
- Receipts
- How much monitoring do you need?
- What do you do with any items left over at study’s end?
CONSIDERATION 4: DOCUMENTATION AND MONITORING

Principle: You need evidence that the payment went to the study participant

- Best: receipt signed by the participant receiving the payment
- Acceptable, if necessary: two study personnel sign for payments distributed, with senior fiscal officer (SFO) signature on log
- Exceptions: Checks cut by A/P, ClinCard reloads, merchandise of minimal value, class credit
- Chain of custody: keep a log if multiple people are handling payments
Principle: The person you pay should have participated in the study

- What if the participant
  - Reports a lost check/eCard, gets a replacement and uses both?
  - Said s/he completed the protocol but didn’t?
  - Is not the same person as the one screening?
  - Lied at screening to get into the study?

- Strategies for reducing cheating
MONITORING TO PREVENT DIVERSION AND LOSS

- Catch problems early with regular monitoring
- Who is the monitor?
  - Not custodian
  - Department vs. OSP
- Amount requested = amount unspent + amount properly documented as given to participants
RECORD RETENTION

- Keep receipts with study documentation
- Check your sponsored research agreement for record retention requirements. Normal requirement: active plus 10 years.
- If it is not OSP funded, unclear (4 or 5 years?)
QUESTIONS?