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Participant Compensation: Ethics, Taxes and Common Practices





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Participant Compensation Theory & Ethics





Theoretical Models

- Free Market
- Wage Payment
- Reimbursement
- Appreciation
- Fair Benefits
- · Intentional Inducement





(Free) Market Model

- Views research participants as paid labor
- Paid for:
 - Services completing surveys
 - Procedures blood collection
 - Specimens blood, tissue
- Based on:
 - Time, Effort, & Inconvenience
 - Risk





(Free) Market Model

- There should be no upper limit
 - Payments based on market conditions
 - May rise or fall relative to labor supply
- May be too high





Wage Payment Model

- Free Market Model with restrictions
- Payment is equivalent to hourly wage of an unskilled laborer taking similar risks
- Concern for potential exploitation of participants by sponsors through artificially low wages
- · May be too low





Free Market & Wage Payment Models

- May apply to Phase I studies
- Do not apply to Treatment protocols
- Do not apply to child participants





Reimbursement Model

- · Views research participants as volunteers
- Revenue neutral
- Paid for expenses of participation
 - Travel, Parking, Babysitting, Lost wages
- Not paid for time
- Can apply to parents of child participants
- Does not apply when no expenses are incurred by participants





Appreciation Model

- Payment is token of thanks for the contribution to the research
 - Nominal amount of money
 - Gift or Gift certificate / card
- · Can apply to child participants
- Can apply when no expenses are incurred by participants





Fair Benefits Model

- Characterizes payment as a form of sharing of benefits among partners in research
- Not a transaction between the investigator and the research participant
- · Payment is a benefit
- Could skew risk / benefit ratio





Intentional Inducement Model

- Inducement may be helpful / necessary for enrollment, due to:
 - Competition
 - Research savvy potential participants
- If the research is approvable, inducement is acceptable
 - Encourage, Motivate, Persuade





Ethical Principles (Belmont)

- Respect for Persons
 - Autonomy
- Beneficence / Non-maleficence
 - Risk / Benefit analysis
- Justice
 - Fairness





Enticement / Inducement

- Greater than expenses of participation
- Represents undue influence
- Violates voluntariness of respect for persons
 - Financial inducements are designed to get people to do something they would not otherwise do





Enticement / Inducement

- It is unethically paternalistic for the IRB to prevent people from doing something they want to do as long as they understand the implications of their decisions.
 - If true, then payment is a benefit.





Enticement / Inducement

- · Violates justice
 - Likely to result in economically disadvantaged people bearing a disproportionately large share of the risks of research
 - Not true if participation is beneficial & not solely burdensome





Enticement / Inducement

- Signal of risk
 - Riskiness inferred by amount of \$\$
 - Could imagine high \$\$ = more risk; more consideration
 - Could imagine low \$\$ = low risk
- May counter therapeutic misconception
 - Would enhance autonomy





Children

- (All Enticement / Inducement concerns) +
- Limited capability to understand risk = inability to adequately assess risk / benefit relationship
- Adolescents believe themselves to be invincible
- · Appreciation of role and value of money
 - Children < 9 years No
 - Children >= 9 years Yes





Parents

- · Payment for child's participation
- Reimbursement not an issue
- Potential exposure of child to risk > that which parent would otherwise deem appropriate
 - Unintentional
 - Intentional





CCHMC Research Policy R-08

- Human Research Protection Program : Research Participant Recruitment Methods, Materials & Compensation
- 2.7.1 Compensation
- The purpose of this policy is to establish <u>standards</u> for Recruitment Methods, Materials, & Compensation in order to <u>minimize coercion</u>, ensure equitable selection of participants, and fulfill the regulatory requirements of informed consent, while <u>minimizing the participants' personal expenses</u> for participating in Human Subjects Research.





CCHMC Research Policy R-08

- 2.7.1. Compensation to a participant (or to the participant's authorized representative) for participating in research is a recruitment incentive and is not considered a benefit.
- 2.7.2. The amount of reimbursement should be <u>comparable</u> to other research projects involving similar time, effort, and inconvenience.
- 2.7.3. The amount of payment and the proposed method and timing of disbursement is <u>neither</u> <u>coercive nor presents undue influence.</u>





CCHMC Research Policy R-08

- 2.7.4. Gift certificates, small amounts on gift cards, and merchandise are acceptable forms of compensation if the certificate, gift card or merchandise abides by this policy.
- 2.7.5. Any compensation or reimbursement should accrue as the study progresses and not be contingent upon the participant completing the entire study.
- 2.7.6. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.





CCHMC Research Policy R-08

- 2.7.7. Disallowed compensation includes:
- 2.7.7.1. Payment of a Finder's Fee is a violation of the AMA Code of Ethics E-6.03 and is strictly prohibited.
- 2.7.7.2. Payment of Recruitment Bonuses is strictly prohibited.
- 2.7.7.3. For research involving children, the investigator and the IRB must ensure that proposed compensation is adequately <u>targeted to the</u> <u>participant</u> and <u>not entirely to parents or authorized</u> <u>representatives</u> of the participant.





CCHMC Research Policy R-08

- 2.7.7.4. Compensation may not include a coupon good for a discount on the purchase price of the Test Article once it has been approved for marketing.
- 2.7.7.5. Opportunities to participate in raffles or other games of chance are not acceptable forms of compensation in accordance with Ohio law (ORC Sections 2915.04 and 3763.01).





FDA Information Sheet

Payment to Research Subjects

- · Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive.
- · Financial incentives are often used when health benefits to subjects are remote or non-existent.
- The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence [21 CFR 50.20].





References

- Amdur, R. J., & Bankert, E. A. (2007). Institutional review board member handbook (2nd ed.). Sudbury, MA: Jones and Bartlett Publishers, Inc.
- Bagley, S. J., Reynolds, W. W., & Nelson, R. M. (2007). Is a "wage-payment" model for research participation appropriate for children? *Pediatrics*, 119(1), 46-51.
- 51.
 Bankert, E. A., & Amdur, R. J. (2006). Institutional review board management and function (2nd ed.). Sudbury, MA: Jones and Bartlett Publishers, Inc.
 Cryder, C. E., London, A. J., Volpp, K. G., & Loewenstein, G. (2010). Informative inducement: Study payment as a signal of risk. Social Science & Medicine, 7/1/31 A5R-A6A
- 70(3), 455-464.

 Iltis, A. S. (2006). Payments to children and adolescents enrolled in research: A
- Resnik, D. B. (2007). Payments to research subjects: Ethical issues





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Participant Compensation Tax and IRS Implications





Reimbursement or Compensation?

- Reimbursement
 - Payment for expenses incurred as a result of participation in a study (i.e. travel-related expenses)
 - Requires documentation to support expenses in accordance with CCHMC Policies and Guidelines (ACC-002, ACC-003, etc.) such as receipts, mileage logs, etc.
- Compensation
 - Payment to incentivize research subjects to participate in a study (i.e. time and effort)
 - Payment made regardless of whether any expenses are actually incurred by the research subject





Vendor Setup Requirements

- Form W-9, Request for Taxpayer Identification Number
 - US Residents with an SSN, EIN, or TIN
 - Required for CHMC to issue payment by check to a research study subject (reimbursement or compensation)
 - Provides information necessary for year-end tax reporting if required
- Form W-8 BEN, Certificate of Foreign Status
 - Non-resident equivalent of W-9
 - Required in order to avoid 30% mandatory backup withholding





Tax Considerations

- Reimbursement
 - Payment for documented expenses in connection with a CHMC business purpose is generally not considered taxable income to the payment recipient (IRC Sec. 274)
- Compensation
 - Payment for participation in a study without documentation of expenses incurred is considered taxable income to the study participant <u>regardless of the dollar amount involved.</u>





Year-End Tax Reporting

- Form 1099-MISC, Miscellaneous Income
 - Required if CHMC makes payments in excess of \$600 per calendar year for all non-employee compensation.
 - Reimbursements
 - Not required to issue 1099-MISC provided that documentation is sufficient to indicate payment is for reimbursement and not compensation
 - Compensation
 - Aggregate amounts paid during calendar year when considering \$600 threshold, may include reimbursements if documentation not sufficient
- Form 1042-S, Foreign Person US Source Income
 - Required if CHMC makes a payment to a non-resident and witholds 30% backup withholding.





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Participant Compensation Procedures and Application





Compensation Procedures

- Research Participant and Parent/Guardian Compensation Guidelines
- Management of Study Funds used for Research Participant Remuneration





Compensation Guidelines

A systematic approach for research participant compensation is necessary to ensure that all compensation for study participation is consistent across similar studies. Research participants/parent/guardian may be reasonably reimbursed for their time, effort and inconvenience involved in study participation provided the amount and schedule of reimbursement have been approved by the IRB and the Sponsor.





Compensation Guidelines

General

- Method, amount, and schedule of compensation are included in IRB approved written Informed Consent form provided to research participants and parents.
- Compensation can be in the form of check, cash, gift certificates/card to local stores or movie theaters, or savings bonds made payable to the research participant or any combination.





Compensation Guidelines

General

- Compensation is prorated in a manner approved by the IRB.
- Compensation may be provided at the time of study visits or mailed to a home address.
- Compensation that accrues per visit is <u>not</u> contingent on study completion.





Compensation Guidelines

Specific

- If round trip transportation to the CCHMC research site is greater than 100 miles, consider having the sponsor reimburse for expenses associated with meals, overnight hotel accommodations and travel.
- Petty cash (for food) or meal tickets may be provided to research participants and parents/guardians.
- If a check is issued or total compensation is greater than \$600.00 the recipient should complete a W-9 form for tax reporting purposes.





Compensation Guidelines

Payment Recommendations

- These recommendations are intended as guidelines in calculating compensation to research participants and/or parents/legal guardians.
- Hourly study participation rate based upon initial and reasonable estimate of visit time as noted in the informed consent (not actual time).





Compensation Guidelines

Payment Recommendations

- First hour: \$25.00/hour
- Second hour up to ten hours: \$15.00/hour
- After ten hours, additional hours: \$20.00/hour
- Minimally invasive procedures: \$15.00
- Invasive procedures (i.e. IV insertion): \$20.00
- Completion of study document (i.e. diary): \$5.00
- Special circumstances: based on intensity
- Mileage reimbursement: allowable institutional rate per mile





Compensation Guidelines

Early Termination

 Research participants who are enrolled in a study but do not complete the entire study are compensated based on the IRB approved prorated payment schedule outlined in the Informed Consent document.





Management of Study Funds

Consistent process for:

- Requesting
- Storing
- Distributing
- Tracking





Management of Study Funds

Study funds refer to:

- Cash
- Check
- Gift certificates
- Merchandise
- Other transferable compensation





Management of Study Funds

Requesting study funds:

Cash

- · Designate an authorized person
- File a signature card with the cashiers office
- · Complete the petty cash form

Check

Follow the current online PeopleSoft check request process





Management of Study Funds

Requesting study funds:

Gift Certificates and Merchandise

- Designate an authorized person
- Submit a check request payable to the company issuing the gift certificate or merchandise.





Management of Study Funds

Storing study funds:

- Study funds must be secured in a safe or similar containment.
- The study fund receipt forms and tracking form must be stored in secured area, separate from the study funds. An electronic, password protected site is acceptable.
- Protective Services can be consulted to evaluate if storage is secure.





Management of Study Funds

Distributing study funds:

- The designated research person will complete the Study Fund Receipt form and obtain the signature of the person (or parent/ guardian) receiving the study funds.
- If the study includes a substantial number of participants, the Study Fund Receipt Log may be used as an alternative to the Study Fund Receipt.





Management of Study Funds

Tracking study funds:

- Enter the amount of the study fund distribution and the calculated study fund balance on the Study Fund Tracking form. The balance on the form and the actual study fund amount remaining in storage must reconcile.
- A separate Study Fund Tracking form must be completed for each different type of study fund offered, regardless if the funds are allocated to the same study. A new Study Fund Tracking form must be initiated every time new funds are obtained.





Management of Study Funds

Tracking study funds:

- At the completion of the study or upon requesting additional funds, remaining funds from the previous request must be deposited back into the original account from which it was drawn.
- · Funds should never be transferred to another study.
- If the remaining study funds are non-cash in nature (gift certificates or merchandise), the Accounting department should be contacted to determine appropriate disposition.





Case Scenarios

In collaboration with your assigned work group, please attempt to answer the following questions for each case scenario:

- 1. Would you provide reimbursement and/or compensation?
- 2.Who is the recipient(s)?
- 3.If you determine compensation is appropriate, how much (per visit/ total) would you recommend?
- 4.Other considerations?





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