Study Participant Incentives: The IRB’s Dos and Don’ts

Adriana Brigatti JD, MPH, LLM, CIP, CHPC
Director, Research Regulatory Affairs

October 2012
What are Participant Incentives
History of Incentives in Research

- 1820s - William Beaumont (father of gastric physiology)
- Patient: Alexis St. Martin — a French Canadian voyageur suffering from an incompletely healed gunshot wound to the stomach
- Incentives: Food, lodging, clothing, and $150
- Study: St. Martin’s stomach contents for one year
History of Incentives

• 1900: American military surgeon Walter Reed
• Incentive: $100 in US gold
• Study: To allow themselves to be bitten by infected mosquitoes in the famous yellow fever experiments
• Additional $100 if the participants consequently contracted the viral disease.
Types of Study Incentives
Motivators of Increased Use of Incentives in Research

- Voluntary nature of participation in research activities
- Time limitations to achieve accrual targets
- Polices requiring the inclusion of minorities in research
- Hard to reach populations
- High mobility of population and difficulty with follow-up activities
Current Trends

- Widespread practice to pay subjects in the US
- Wide spectrum of types of research,
- Variation according to disease or medical subspecialty
  - More common: Asthma, HIV, diabetes, or dermatological research trials
  - Less common: Oncology or cardiovascular trials
Welcome to Paid Clinical Trials

Depression Research Study
Suffering from Major Depressive Disorder? Join our research study.
midresearchstudy.com

Are You Depressed?
Find out if you may pre-qualify for our clinical research study.
www.MyDepressionStudy.com

Paid Research Studies - Search By Location

- United States
  - Alabama, Alaska, Arizona, Arkansas more...
- Australia
  - Capital Territory, New South Wales, Northern Territory more...
- Canada
  - Alberta, British Columbia, Manitoba more...
- China
  - Beijing, Changchun, Changsha more...
- France
  - Amiens, Auvergne, Angers more...
- Germany
  - Aachen, Augsburg, Berlin more...
- Greece
  - Athens, Larissa, Thessaloniki
- India
  - Ahmedabad, Bangalore, Chandigarh more...
- Ireland
  - Cork, Dublin, Galway more...
- Israel
  - Akiva, Ashkelon, Bat Yam more...
- Italy
  - Bari, Bolzano, Catania more...
- Japan
- Local Research Study
  - Local research study enrolling for Anthraxis pain, enroll today.
  - ResearchFunds.com

Sponsors/Recruiting

- Sponsor’s Login
- Create an Account
- Paid Clinical Trials
- View/Edit Account
- View/Edit Listings
- Volunteer Database

Searching for Clinical Trials?

Clinical Trial Profiles
Register Your Clinical Trial Profile with us and let Clinical Trial Recruiters Find You!

- Fast
- Free
- Anonymous

Click to Register
Ethical Concerns

• Risk of undue influence
• Risk of coercion to participate
• Commodification - Risk of compromising the dignity of study subjects.
• Risk that economically disadvantaged populations may bear most of the risk of research participation
Commonly Used Forms of Study Incentives

- Payment to subjects for time and expense
- Payment for time and effort
- Retention incentives
- Finders fees
- Bonus payments
- Participation as a form of receiving medical treatment
Model of Payment for Participation of Research Subjects

• Market
• Wage-Payment
• Reimbursement
• Appreciation
Regulatory Standards

• The US Code of Federal Regulations requires that informed consent be obtained “under circumstances . . . that minimize the possibility of coercion or undue influence”

• An inducement in clinical research, as defined in *The Official IRB Guidebook*, is deemed undue and therefore troublesome if it is so “. . . attractive that [it can] blind prospective subjects to potential risks or impair their ability to exercise proper judgment . . .”
Study Incentives Analysis

- Nature of the study
- Nature of participant contributions
- Vulnerabilities
- Institutional or organizational guidelines
- Local societal and cultural norms
- Payment information should also be included in consent forms and other materials
IRB Application Must Include

• Rationale for payment
• A description of all plans to pay subjects, whether in cash or in kind
• How the dollar amount is calculated; how and when payment will be made
• Services or other non-cash benefits subjects will receive
• Reimbursement for travel and other expenses subjects will receive, such as parking, transportation, lost wages, child care
IRB Don’ts

• IRBs do not consider payment a benefit to offset research risks when deciding whether or not to approve a study.
• Unacceptable risks cannot be made acceptable by offering money to subjects.
• IRBs assess the justification for and the amount and schedule of payment and decide whether these variables are appropriate given the particular study and the population to be recruited.
IRB Dos

• Certificates are preferred to money
• Prorating payment for studies involving multiple visits minimizes the possibility of inappropriately influencing someone to remain in a study just to receive a lump sum payment at the end of the study
• Payment according to actual time and procedures completed is consistent with offering money as compensation for a subject’s time and inconvenience
Pediatric Considerations

- Children do not provide their own consent to research but are enrolled by their parents or legal guardians.
- Payment to parents for their child’s research participation could potentially sway parental decisions in favor of participation since there is no personal risk to themselves.
Pediatric Considerations

• Making it possible for a child to participate in research can be inconvenient and costly for parents, and the amount of risk children can be exposed to in research is strictly limited by federal regulations.

• The American Academy of Pediatrics recommends the giving of gifts instead of money to children in a post-trial appreciation model.
Children’s National Human Subjects Protections Policy

• PROCEDURE: RA:HRPP:08.08P

• Children’s National allows incentives under the four models of payment to study subjects

• The IRB will consider the protocol, including the time commitment and the proposed procedures

• The IRB does not have a set list of recommended remuneration amounts for specific tests or visits, nor does it require that one payment method (gift cards, cash, etc.) be used
Children’s Policy-
Investigator Responsibility

• Specify the types of payments to be offered
• Provide information regarding each category
• The CNMC IRB protocol application form and informed consent document(s) must describe in detail when the subject will receive the remuneration, what will be provided (gift card, cash, voucher, check) and other appropriate details such as grantor requirements
Children’s National Policy
IRB Review

• The IRB will not approve lotteries or prize drawings for individuals who participate in research.
• The IRB may also require changes in the amount and/or type of payment, if deemed appropriate.
• Any change or modification to approved amounts and/or types of payment must be submitted to the IRB as a protocol modification.
Children’s National Policy

Pro-Rated Payment

• Investigators may not require that a subject complete the research in order to receive compensation

• If a subject withdraws from a study, he or she must be offered payment for the completed portion of the study

• Ideally, payments should be provided per visit instead of waiting until the subject completes all, or a group, of the study requirements and then issuing payment for the entire study
Children’s National Policy
Internal Revenue System Reporting

• The Internal Revenue Service (IRS) requires that anything of value (including monetary payments) which is provided equal to or greater than $600 annually must be reported as income. Subjects should be informed of this requirement as part of the consent process.
• The “income” is assigned to the person who receives the remuneration, which is not necessarily the study subject when he or she is a minor.
• The Internal Revenue Service (IRS) requires reporting of payments in excess of $600 per calendar year on Form 1099-Misc.
Children’s National Policy
Internal Revenue System Reporting

• The forms require that name and social security number of the participant be collected on a Form W-9 and released to the CNMC Accounts Payable Department to process the Form 1099-Misc

• The collection and release of this information must be addressed thoroughly in the consent documents
Children’s National Policy
Finders Fees

CNMC prohibits the following:

• Payments to professionals in exchange for referrals of potential participants ("finder’s fees");

• “Bonus payments” designed to accelerate recruitment that are tied to the rate or timing of enrollment;

• Payments to participants in exchange for referrals of potential participants ("finder’s fees") unless they are judged not to increase the possibility of coercion or undue influence on participants by using unreasonable compensation or unreasonable conditions for distribution of compensation.
Case #1

- Study: pediatric glaucoma drop
- Drug has been approved in adults and it is commonly used off label in children
- Procedures: One week of drops once a day in both eyes even if only one eye is affected
- Risks: burning, irritation, redness, change of eye color that could be permanent and, increased length and thickness of eyelashes
- Child Incentive: Ipad plus $50.00 to buy apps. Requires participation in the totality of the study
- Parents get reimbursed $400 for time and effort
Case #2

- A new vaccine study has been proposed to be implemented in the army to protect soldiers against endemic diseases in the Pacific. As incentive, participants will receive 3 days of leave.
Case #3

• A contract is revealed showing that a private Contract Research Organization has conducted the same vaccine trials conducted in the army on civilian healthy volunteers offering a payment of $5,400 for participation. The consent form raises the spectrum of a host of potential side effects “including death.”
Case #4

- In a Scottish study healthy volunteers are paid €600 to drink orange juice laced with pesticides.
- In the United States the Environmental Protection Agency (EPA) announces that it will be considering guidelines to allow pesticide testing in humans. In accordance with the Food Quality Protection Act of 1996, the EPA must review 9,000 pesticides currently on the market to ensure they meet new safety standards.