Should Research Subjects be Paid?
How much is too much? How can we standardize payment?
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Disclosure

I have relevant financial relationship(s) with respect to this educational activity with the following organization(s):

Name of Organization: Fresenius Medical Care North America
Role: Director of Clinical Studies
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How much is too much? How can we standardize payment?

Learning Objectives:
1. Identify models of payment
2. Describe the advantages and disadvantages of each model
3. Illustrate why standardizing payment and using the “living wage” model benefits both the researcher and the trial participant.
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• Researchers offer money to both healthy and ill subjects
  – as an incentive to enroll in research
  – as compensation for research participation

• Institutional Review Boards (IRBs) aim to protect human subjects by determining whether the payment is ethical.
  – Concerned that payment may coerce or unduly influence subject to participate
  – May “blind” subjects to the risks
  – Compromise voluntariness of consent
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• Bioethicists also express concern that
  – Large payments will “crowd out” non-commercial researchers who do not have the resources to compete
  – Unfairly small payments will exploit subjects who participate in research as a way to earn money

• Laws, regulation and guidelines that govern conduct of studies do not provide *specific* guidance about payment.
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• “An investigator shall seek such consent only under circumstances that provide the prospective subject.....sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence”.

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• IRB Guidebook on undue inducement:
  • “may be troublesome because 1) offers that are too attractive may blind prospective subjects to the risks......and 2) they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling...”
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• “Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance”.
• Undue influence “occurs through an offer of excessive, unwanted, inappropriate or improper reward or other overture in order to obtain compliance”.

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• Concerns about ‘undue inducement’ are misplaced.
• Independent review of research precludes trials from exposing participants to excessive discomforts and risks.
Essential Elements of Ethical Research

• Valuable scientific question
• Valid scientific methodology
• Fair subject selection
• Favorable risk-benefit evaluation
• Independent review
• Informed consent
• Respect for enrolled subjects


Essential Elements of Ethical Research

• If payment is standardized so it is more or less comparable to other unskilled money-making opportunities, we can minimize the potential that money will unduly influence an individual to participate in a study against his or her best interests.

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- Researchers and IRBs use a variety of payment models
- Include market-based incentive, wage-payment, reimbursement for lost wages, risk-based, tokens of appreciation etc.
- Wide variation in practice and inconsistent judgments even within an institution

Dickert and Grady argue:
- that the wage payment model is superior
- it is the only model that satisfies the requirements of justice
- all subjects make a similar contribution when they participate in a study
- Subjects within and across research studies should get similar treatment

- N. Dickert, C. Grady, 'What is the price of a Research Subject? NEJM 341, no.3 (1999): 198-203
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• “........participation in research requires little skill but does require time, effort, and the endurance of undesirable or uncomfortable procedures.”
• “ Participation in research is like unskilled labor.”

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• Ideal payment seems to be an amount that avoids the problem of undue inducement, crowding out and exploitation
• A standard payment formula is needed to ensure all subjects are treated equally
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• The Nonfarm Production Wage model
  – $23.29/hr January 2012
  – Unlikely that an unskilled worker will have many options for earning $23.29/hr
  – Undue inducement!
  – Non commercial studies would suffer from poor enrollment

• The minimum wage model
  – Lowest hourly wage that employers can legally pay their employees
  – May prevent undue inducement and crowding out
  – ? Too low. Exploits individual subjects and socially and economically disadvantaged groups
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• The living wage campaign calls for wages sufficient for workers to support themselves and their families.
• Premised on the idea that tax dollars should not fund poverty level jobs.
• Many ways to calculate a living wage

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• Sample Living Wage Formulas:
  – Cost of food and minimum dietary requirements
  – Cost of housing and HUD standard that no more than 30% of a person’s gross monthly income should be spent on housing.
  – Federal poverty level
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• Federal Poverty Level Formula:
  • If health benefits are not provided, then
    – 1. Multiply the poverty line for a family of four by 125% and
    – 2. Divide by the number of hours in a standard work year (2000).

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• The 2009 poverty level for a family of four was $22,050:
  • $22,050/year x 110% ÷ 2,000 hours/year = $12.13/hour
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• Guidance could provide sample formulas to IRBs and allow them to choose or
• Could specify one formula for all IRBs to follow
• Advantage of one formula is simplicity
• It could be updated each year

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• Many studies would not meet their enrollment goals if they did not offer a financial incentive for participation
• Absent guidance, current practices can violate ethical requirements for research on human subjects
• A formula for calculating payment amounts could resolve some of these ethical issues
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- Questions?