Misconceptions About Coercion and Undue Influence

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Disclaimer

- The views expressed in this talk are my own. They do not necessarily – in fact they probably do not – represent the views of the National Institutes of Health or the Department of Health and Human Services

Background

- Research participants are commonly offered payment
- Payment is offered to healthy volunteers and patient volunteers
- Payment is offered in all kinds of studies
- Wide range of payment amounts ($5-2000), median $155, (one study of 467 protocols)
Yet...

- There remains strikingly divergent views about the appropriateness of paying research subjects

Why do we pay research subjects?

- Reimbursement
- Compensation for time and burdens
- Compensation for risk
- Avoid exploitation
- Incentive for recruitment
- Some reasons are more accepted than others

What do we worry about?

- Commodification
- Skewed sample
- Subject fraud (hiding exclusion conditions)
- Coercion
- Undue Influence
Coercion or undue influence?

- US Code of Federal Regulations require that informed consent be obtained “under circumstances...that minimize the possibility of coercion or undue influence”
  - 21CFR.50
  - 45CFR.46

Anecdotal Evidence

- Anecdotal evidence suggests that many IRB members think that payment or offers of medical care do or can coerce or constitute undue influence
- We are inclined to think that these worries are often based on misconceptions about these concepts

Two Objectives of Our Study

- Find out what IRB members believe about coercion and undue influence
- If we find that they believe what we believe they believe, then we want to show that those beliefs are based on misconceptions
Background

• What do IRB members and others who are making decisions about research studies think about payment, coercion, undue influence?
  – How concerned are they about payment?
  – What factors are considered when they make decisions about payment to research subjects?
  – How do they understand coercion and undue influence?

Methods

• Cross-sectional, descriptive, on-line survey
• Random sample of 1800 (+ 269) from PRIM&R database—individuals involved in human subjects research
• Advance letter - information about the study, that participation was voluntary, and responses anonymous
• $5 in letter
• Email with link to on-line survey


• Survey pretested - NIH & UVA Center for Survey Research

• ~ 80 (mostly) multiple choice or Likert questions

• Five domains:
  • Level of ethical concern about paying subjects
  • Reasons to offer money to research participants
  • Attitudes about coercion and undue influence
  • Hypothetical scenarios
  • Demographics
Results: Respondent Characteristics (n=610)

- 84% Non-Hispanic White
- 70% Female; Average age 51
- 65% masters or doctorate education
- Geographically diverse
- 92% in a job related to human subjects research
- 56% current or past IRB members

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Results: Reasons for paying and views about paying healthy and patient volunteers

<table>
<thead>
<tr>
<th>reasons for paying</th>
<th>healthy volunteer</th>
<th>patient volunteer with no prospect of benefit</th>
<th>patient volunteer with a prospect of benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>offer money</td>
<td>84.4%</td>
<td>78.7%</td>
<td>71.1%</td>
</tr>
<tr>
<td>reimburse for expenses</td>
<td>97.0%</td>
<td>95.4%</td>
<td>92.8%</td>
</tr>
<tr>
<td>compensate for time, effort, inconvenience</td>
<td>68.6%</td>
<td>90.5%</td>
<td>84.3%</td>
</tr>
<tr>
<td>offer money as an incentive</td>
<td>58.4%</td>
<td>56.2%</td>
<td>52.3%</td>
</tr>
<tr>
<td>offer money to compensate for risk</td>
<td>66.4%</td>
<td>86.8%</td>
<td>84.6%</td>
</tr>
</tbody>
</table>

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Results: Respondent views on coercion and undue influence

<table>
<thead>
<tr>
<th>percent of respondents who agreed or strongly agreed</th>
<th>Not... it is coercion</th>
<th>Not... it is undue influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>... are threatened with harm</td>
<td>91.2%</td>
<td>---</td>
</tr>
<tr>
<td>... will participate with payment when otherwise they would not</td>
<td>64.8%</td>
<td>81.0%</td>
</tr>
<tr>
<td>... feel they have no reasonable alternative but to participate because of payment</td>
<td>81.6%</td>
<td>79.2%</td>
</tr>
<tr>
<td>... ability to accurately perceive risks and benefits is distorted when offered payment</td>
<td>---</td>
<td>98.3%</td>
</tr>
</tbody>
</table>
Scenario 1

A researcher has developed a new vaccine against malaria. The researcher is recruiting healthy adult volunteers for a multi-site, Phase I study to determine if the vaccine is safe in humans.

Sites are US suburb, US inner city, Rwanda

No prospect of direct benefit for the subjects.

Initial visit involves a physical examination, blood draw, and urine test. Six additional visits over 4 months each expected to last one hour.

Injection of vaccine at first, second, and third visits. At fourth, fifth, and sixth visits, vital signs will be checked, and blood will be drawn.

Scenario 2

An investigator developed a new drug to treat leukemia. Adult patients are being recruited for a study of efficacy.

The study is more than minimal risk, but there is a prospect of direct benefit.

Patient volunteers will be admitted to the hospital for one week and to receive a dose of the new drug. During hospitalization, additional research-related procedures not for clinical reasons: PET scan, bone marrow biopsy, and blood draws.

Every four weeks for 24 weeks, repeat admission and procedures.

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## Results: Factors considered in determining appropriate payment amounts

<table>
<thead>
<tr>
<th></th>
<th>Considered in determining payment amount for phase I malaria vaccine trial</th>
<th>Considered in determining payment amount for leukemia treatment study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considered factors</td>
<td>US suburb</td>
<td>US inner city</td>
</tr>
<tr>
<td>Reimbursement for expenses</td>
<td>67%</td>
<td>66.7%</td>
</tr>
<tr>
<td>Compensate for time, effort, inconvenience</td>
<td>80.1%</td>
<td>82%</td>
</tr>
<tr>
<td>Other money, as an incentive</td>
<td>30.5%</td>
<td>31%</td>
</tr>
<tr>
<td>Other money, to compensate for risk</td>
<td>30%</td>
<td>31.6%</td>
</tr>
</tbody>
</table>
Questions about the scenarios

Mary, a resident of a US inner city, tells one of the research nurses: "I would normally not have enrolled in this [malaria vaccine] study, but I recently lost my job, and I need the money. I don’t feel like I have any alternative but to participate."

1. Do you think Mary has been coerced?
   – Yes (24%)

2. Do you think Mary has been unduly influenced?
   – Yes (64%)

Questions about scenarios

The leukemia study is approved by an IRB with a $2,500 incentive payment. John enrolls and tells the principal investigator: “The bills have piled up since I got sick, and I feel like my only option is to participate in this study. I need the money.”

• Do you think John has been coerced?
  – Yes (27%)

• Do you think John has been unduly influenced?
  – Yes (70%)

Questions about scenarios

Steve enrolls and tells the principal investigator: “I don’t have health insurance. I don’t care about the money, but by enrolling in this study, I can get the medical care I need. I feel like I have no alternative but to participate.”

• Do you think Steve has been coerced?
  – Yes (27%)

• Do you think Steve has been unduly influenced?
  – Yes (60%)
Conclusions

• Ethical concerns persist among research ethics professionals about offering payment to research subjects

• Payment as reimbursement or compensation for time and inconvenience are more acceptable than payment as incentive or as compensation for risk

• Appears to be a divergence between views about coercion and undue influence and application to cases

Need for more research

• What decisions do IRBs actually make about payment?

• Do investigators design payment based on concerns the IRB might have?

• How do research subjects view payment?
  – Does payment affect recruitment?
  – What trade-offs do participants make?
  – Do people participate in studies they find objectionable because of money?

From Data to Argument
The Basic Problem

• To the extent that IRB members’ attitudes regarding payment are ethically sound, they appropriately influence payment practices
  — studies should not be approved if participants’ consent is likely to be compromised by coercion or undue influence.
• If IRB members’ concerns are based on conceptual or ethical misconceptions, unnecessary limits may be placed on payments to research participants and impede valuable research without ethical cause.

Our Thesis

• Many of the prevalent concerns about payment are largely misguided.
• Payment never coerces.
• Payment raises ethical concerns with respect to consent only when it unduly influences participants by distorting their perception of research risks and benefits.
• In the absence of evidence that such distortions occur, IRBs should be reluctant to conclude that offers of payment undermine the validity of consent.


Coercion

• The *Belmont Report:* “Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.”
• This definition states that coercion requires a *threat of harm*
APA: Ethical Principles of Psychologists and Code of Conduct

8.06 Offering Inducements for Research Participation  
(a) Psychologists make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.

Coercion

- Most respondents agreed that “Research subjects are coerced only if they are threatened with harm if they don’t participate in research” (emphasis added).
- We suspect that most read the question as asking whether they thought someone is coerced “if” rather than “only if” they are threatened with harm.
- Many also agreed with formulations of coercion that do not involve a threat of harm.

Coercion

- Offers of payment do not coerce just because they get someone to agree to participate in research when they would otherwise not.

- There are numerous ways of motivating people to do things that they would otherwise not do:
  - A persuades B to give blood or go to a movie or invest in a mutual fund.
  - A offers the teenager next door $20 to mow his lawn.
  - As a general proposition, offers do not coerce.
  - Offers can be indecent and immoral but they do not coerce.
Coercion

• Some respondents said that people are coerced to participate in research when they have no reasonable alternative but to consent to participate.

Coercion

• No reasonable alternative view is false
• We do not say that a patient who agrees to surgery or chemotherapy because the only alternative is death has been coerced to consent or that her consent to treatment is involuntary or invalid.
• We do not describe people as coerced if they take an unpleasant job in order to provide for their families.

Coercion

• What would constitute coercion to participate in research?
• If patients have a right that their physicians not abandon them if they refuse to participate in research, then the implicit or explicit threat of abandonment may constitute coercion.
• But such cases involving threats aside, coercion to participate in research is probably rare.
• Does not apply to offers of payment
Coercion

• We should be concerned when a respondent says, “Coercion has come to mean something more along the lines of simple influence in the IRBs I have worked with - not the meaning it has in other contexts.”
• Why should the meaning of coercion in IRBs differ from its meaning in other contexts?
• This respondent’s IRB has adopted an excessively expansive account of coercion that may be used inappropriately to limit the activities of researchers and prospective subjects.

Coercion

• I’m here to reduce your worries
• IRB members and ethicists should simply stop worrying about the coercive effect of payment.
• Offers of payment do not coerce. Period.

Undue Influence

• There is nothing problematic about payment motivating someone to do something they would otherwise not do
• There is nothing problematic about consent in exchange for payment when people reasonably believe they have no other acceptable alternative
• It is not unreasonable to think that the value of payment exceeds the disvalue of the burdens of participation
Undue Influence

- The key is *reasonable* belief
- A’s offer of payment is unduly influential if it is so attractive that it distorts subjects’ evaluation of the risks and benefits of participation.
  - Myopia
  - Tunnel vision

Undue Influence

- The Office for Human Research Protections (OHRP) guidebook for IRBs says “Offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment.”

Undue Influence

- An offer of payment does not constitute *undue* influence if subjects are likely to make a reasonable or rational choice to regard the value of the payment as sufficient to justify the risks or burdens of participation.
- A structural steel worker or lobster fisherman is not necessarily *unduly* influenced by the offer of payment to take on a risky job.
Undue Influence

- There is little evidence that offers of payment distort judgment and some evidence that they do not
- Payment may make subjects more attentive to risk
- Important point is that absent such distortion, payment does not constitute undue influence

Distinguishing Coercion from Undue Influence

- Sliding Scale View
- Distinct Concept View

Sliding Scale View

- Undue influence and coercion lie on a continuum
- Undue influence is a weaker form of coercion
Distinct Concept View

- Coercion compromises the voluntariness of a decision, but not necessarily its rationality.
  - Extortion
- Undue influence compromises the cognitive dimension of decision-making, but not its voluntariness.

Caveat

- We do not know the extent to which these views about payment affect IRB decision-making or whether researchers do not propose payment schedules because they believe they will be rejected.

Conclusion

- If these views do affect decision-making, then IRBs inappropriately limit payment offered to research subjects
  - Deprives researchers of opportunity to conduct research
  - Deprives society of benefits of research
  - Deprives prospective subjects of opportunities to participate when they would benefit from doing so – pseudo-protection
Conclusion

- We should be very reluctant to interfere with win-win-win activities