Vulnerability, Undue Inducement, Coercion & Exploitation in Research

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Vulnerability and Payment/Inducement in Research





Objectives



- Explain the concept of vulnerability and identify some of the vulnerable groups.
- Discuss measures put forward to protect them.
- Describe the role of REC and the investigators in such conditions.
- Discuss payment in research.



What is Vulnerability?



The word vulnerability has two senses:

- "To be exposed to the possibility of being attacked or harmed, either physically or emotionally." Synonyms: defenseless, unprepared, weak, helpless, in danger, at risk.
- 'Liable to temptation or manipulation'.



Recognition of the concept in International Guidelines (e.g. Helsinki & CIOMS)

The guidelines <u>define</u> vulnerability,
 outline the <u>characteristics</u> of vulnerable
 people and emphasize <u>the need to</u>
 <u>protect</u> them from exploitation



Characteristics of Vulnerable people



- Vulnerable persons are relatively (or absolutely) in capable of protecting their own interests.
- They may have insufficient:
 - Power, Intelligence, Education, Resources,
 Strength, or other things
 needed to protect their own interests



Definition: Two Parts



- To be vulnerable, one has to be exposed to the possibility of harm.

 EXTERNAL
- To be vulnerable one has to be substantially unable to protect oneself.
- Both elements are necessary

Definition: To be vulnerable means to be exposed to the possibility of harm while substantially lacking ability and/or means to protect oneself.





Impaired decision making capacity, hierarchical relationships, institutionalized persons/dependent relationships and others



Impaired decision making capacity



- Decision making ability depends on the participants ability to
 - Understand factual information, appreciate
 the situation they are being asked to be in and appreciate the consequences of the decision,
 weigh risks and potential benefits and communicate.
- If a researcher doubts the decisional capacity of a participant, s/he must adequately assess it.

Participants in hierarchical relationships

- Subjects who are junior or subordinate members to the Researchers
 - Examples: students-professors, doctorhospital and laboratory personnel.
- Agreement to participate may be the result of their expectation of better treatment or their fear of retaliation if they refuse to do so.

Institutionalized persons/ Dependent relationships



- Examples: patient- physician, elderly in nursing homes, prisoners etc.
- In case of a dependent relationship it is better if a neutral party takes the informed consent, examples are the research nurse or a qualified collaborator

Other examples for potential causes of vulnerability



- Poverty
- Minorities
- Nomads
- Refugees and IDPs
- Incurable diseases

- Stigmatized diseases
- Disabilities
- Lack of access to medical care
- Gender, sexuality and age



Remember...



People might experience more than one type of vulnerability,
 e.g. poor children



How Broad the Concept is?

- All human beings are exposed (vulnerable) to the possibility of "harm"
- But, not to the same degree

Remember the definition: To be vulnerable means to be **exposed** to a *significant probability* of incurring an **identifiable harm** while *substantially* **lacking ability**/means **to protect** oneself.

Ethical threats of vulnerability

- Unfavorable risk/benefit ratio
- Breach of confidentiality or privacy →
 Social harm
- Lack of access to the benefits of research.....exploitation



Special Protections For Vulnerable Populations



Research on vulnerable groups Needs...

- Special justification for enrolling them as research subjects
- Additional protections during the process of enrolling such individuals.
- More attention from the the PI, REC and through Informed consent document & process to protect them from exploitation.

Special protections includes:



- No more than minimal risks for procedures,
- Permission of the appropriate representative: to supplement the agreement of those individuals incapable on giving consent
- Requiring that the research be carried out only when it is targeted at conditions that affect these groups.

Special protections includes:



- Ensure that the potential for confidentiality breaches is limited.
- Ensure that the interest of the vulnerable group is met: through the inclusion of an advocate of that group in the REC.



Moreover...



- In the case of prisoners the following need to be ensured:
 - Potential benefits not coercive, risks not above what will be accepted by a non-prisoner, fair subject selection not influenced by authorities and participation in research is not related to liberation decisions.

Consent requirements

Research on individuals who cannot decide for themselves require surrogate consent e.g. children and mentally impaired

- The third parties should be competent to act in that person's best interest
- They should be given an opportunity to observe the research as it proceeds to be able to withdraw the subject from the research (Belmont report)

Vulnerable Countries



- Communities in low income and lower-middle income countries (Sudan) are considered vulnerable, because their populations lack basic rights and freedoms that make them particularly open to exploitation.
- Protective measures are put forward by international guidelines e.g. CIOMS.

Conclusion: To protect vulnerable groups



- Perform
 - Appropriate risk-benefit assessment
 - Proper capacity assessment
- Ensure that
 - The necessity requirements are met
 - Proxy decision maker is present (when needed)
 and subject's assent/dissent is respected
 - Independent monitor for the consent process is present





Alexis St. Martin: the earliest paid human subject

- In 1822, accidentally shot in the gut and left with a permanent gastric fistula.
- William Beaumont paid him room, board, and \$150 a year for use of his stomach.

http://www.guineapigzero.com/AlexisStMartin.html



Payment Today

- S
- "Make \$1,000's... Get paid hundreds weekly in additional cash income, parttime, while relaxing in a million-dollar, get paid research study... Yes, there are thousands of cash paying studies and even free medical care available!"
- http://www.rxgetpaid.com



Provision of other goods



 Access to antiretroviral therapy (ART) in preventive HIV vaccine trials & Burial expenses for an autopsy study of cerebral malaria in Malawi.



What do subjects want?



- Interviewed 963 Ugandans
 - Participants (paid/unpaid), decliners, residents of uninvolved communities, and community leaders
 - 72 % said subjects should be compensated
 - 40% money
 - 22% health care
 - 15% food
 - 5% health item



Hence....

- Inducements (بواعث، مشجعات مغریات) are offers
 that get people to do things they would not otherwise do.
- Inducement in everyday life
 - Higher salaries for jobs.
- Inducements in research
 - Any activity to encourage participation.

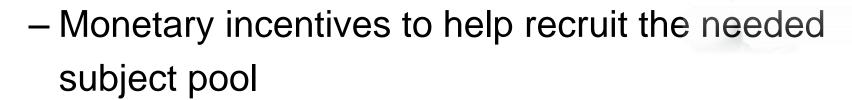


Models of payment in research



Common Models

Market Model



Pure incentive (supply and demand rule)

Reimbursement Model

- Participation should not require financial sacrifice by subjects.
- Reimbursement for expenses



Common Models



- Wage Payment Model
 - Participation is like unskilled labor
 - Working wage: payment for unskilled labor (10\$/hr.)



Summary

- To be vulnerable means to be exposed to the possibility of harm while substantially lacking ability and/or means to protect oneself.
- Vulnerability is the result of certain conditions e.g. impaired decision making capacity, hierarchical relationships, dependent relationships and others.
- When enrolling vulnerable people in research certain conditions need to be observed.

Summary

- The purpose of inducement is to motivate participation in research and it can be in money or other goods.
- There are certain models that researchers follow to determine how should they pay participants.



