

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 define vulnerability, outline the characteristics of vulnerable people and emphasize the need to protect them from exploitation



Characteristics of Vulnerable people



- Vulnerable persons are relatively (or absolutely) incapable 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. **INTERNAL**
- 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.





Vulnerability conditions

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, doctor-hospital 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



Payment in Research



To understand undue inducement,
we need to discuss inducement 😊



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



- **“Make \$1,000's...** Get paid hundreds weekly in additional cash income, part-time, 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 مغريات،) 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**

- Monetary incentives to help recruit the needed subject pool
- 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.



Thank You

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فيكم

