



## Vulnerability in research

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- What is vulnerability?
- Who is vulnerable?
- Why are they vulnerable?
- Changing landscapes
- What should be done if participants are vulnerable

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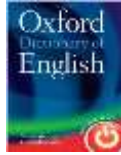
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## Vulnerable



- Exposed to the risk of being attacked or harmed, either physically or emotionally



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## Vulnerable



- Likely to be misled, mistreated, or otherwise taken advantage of in research



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## Vulnerability



- Typically understood in terms of the ability to give or withhold **informed consent**
- Linked to **autonomy**
- **Is a concept that goes beyond the ability to give consent**

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- Identifying who is vulnerable is important to both ERCs and researchers
- Help to direct responsibilities of those involved in research to protect the vulnerable

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### Who is vulnerable?



- Traditionally linked to the capacity to give informed consent
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- Those who are “unable to consent”

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1932 - 1972



1943

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### Nuremberg code

- Has an implicit assumption that all research participants are vulnerable

#### THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the aims and nature of the experiment, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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### Belmont report

- Requirement for informed consent of all research participants
- Mentions those "especially vulnerable"
- Identifies characteristics that signify special vulnerability
  - lack of capacity to consent to research
  - increased susceptibility to coercion or exploitation
  - increased risk of harms

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## Who is vulnerable?



- Population approach
  - Women
  - Pregnant women
  - Fetuses
  - Prisoners
  - Armed forces personnel
  - Children
  - Institutionalized and mentally ill persons
  - Those in a resource poor setting
  - Those socially or economically disadvantaged
  - Limited language proficiency – E/S/T

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## Categories of Vulnerability



- Cognitive or communicative vulnerability
- Institutional vulnerability
- Deferential vulnerability
- Medical vulnerability – nature of illness, ability to obtain treatment

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## Categories of Vulnerability



- Economic vulnerability
- Social vulnerability
- Legal vulnerability
- Study vulnerability – deceived during study/  
not made aware of all aspects of study

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- An individual may be vulnerable due to many reasons

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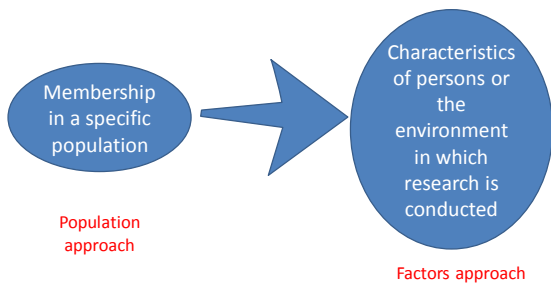
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## Factors approach



- Focus on the specific factors or conditions that may render individuals vulnerable in the particular research setting
- Identifies those who are **relatively** or **absolutely** incapable of protecting their own interests in the respective setting

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## Factors-approach



- Vulnerability is evaluated by asking:
  - what aspects of a person or the circumstances in which the research is being conducted might render this person
    - less able to give free and voluntary informed consent
    - more likely to be exploited
- Emphasis is on the **characteristics** and **circumstances** that contribute to vulnerability

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- **Categorically** restricting research participation of persons who have limited financial or social resources may
  - violate ethical obligations-e.g. ensuring fair subject selection
  - wrongly deny some people the potential benefits of research participation
  - render research results less generalizable

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- “ Special **justification** is required for inviting vulnerable individuals to serve as research subjects

and, if they are selected,

- the **means of protecting** their rights and welfare must be strictly applied.”

- CIOMS

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- When some or all of the subjects are likely to be vulnerable to coercion or undue influence **additional safeguards must be included in the study** to protect the rights and welfare of these subjects.

- If unable to provide the extra precautions needed, **exclusion** of such persons from research

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- Protections offered to individual research participants should correspond to the specific sources of their vulnerability

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- ERCs should evaluate protocols and potential subject populations to determine whether
  - involvement of vulnerable persons is needed
  - protections should be put into place to alleviate vulnerabilities
  - protections have been put in to place to protect the vulnerable

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- Unless there is a **valid justification** for holding that persons necessarily suffer from impaired decision making or are being exploited, coerced, or unduly influenced, **they should not as a group be barred from participation.**

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## Problems with vulnerability



- So many categories - virtually all potential human subjects are included
- When considered as a group – individuals within the group are not distinguished
  - Some might have special features that would need special protection
  - An almost exclusive emphasis on group characteristics might undermine or eliminate the capacity to give consent

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## Problems with vulnerability



- The emphasis on vulnerability can divert attention from features of the research itself, the institutional environment, or the social and economic context that can put participants in harm's way.

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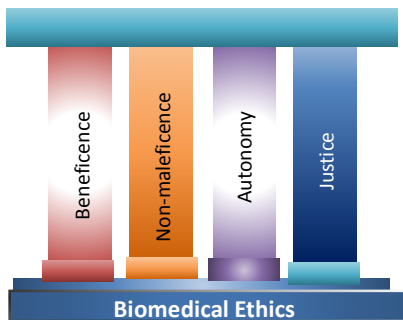
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