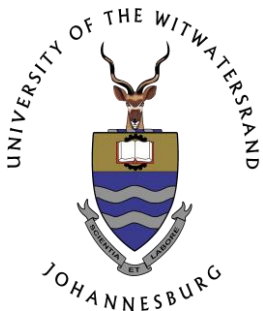


# Vulnerable Groups

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# Outline

- Notion of Vulnerability
- Vulnerability and Exploitation
- Categories of Vulnerability
- Authoritative Documents
- DoH on vulnerability – strengths and weaknesses

# Notion of Vulnerability

- Vulnerability referred to increasingly in health research.
- Linked in most research ethics guidelines and codes to questions of justice in selection of participants, limitations of capacity to provide informed consent, unequal relationships between disadvantaged groups and researchers and sponsors, ... .
- Generally accepted that one of the principle tasks of ethics in research is protecting vulnerable participants from exploitation and other forms of harm
- “Vulnerable” originated from the Latin term “*vulnerare*”, which means “*to wound*”. \*
- Dictionary meaning of vulnerable : “*exposed to being attacked or harmed, either physically or emotionally*”. \*

\*South African Concise Oxford Dictionary

- Being human, by implication, denotes vulnerability.
- All humans exposed at some stage or other to the risk of suffering harm against personal integrity - physical, emotional, psychological and / or spiritual.
- Human vulnerability :
  - intrinsically connected to the essential notion of personal integrity
  - perceived as an inescapable dimension of human life
  - an integral component in the shaping of human relationships.
  - acknowledges that at some point, all human beings may lack the ability to protect themselves from harms which at times may even be inflicted by other human beings.
- While human kind as such is vulnerable, there are individuals, groups and situations for whom greater attention needs to be paid.

- Notion of vulnerability is closely linked with the notion of personal integrity.
  - Where participants are vulnerable, there is potential for their autonomy to be infringed.
  - Impact negatively on their rights – bodily and psychological integrity & human dignity.
- Human beings are moral agents and hence have rights to their own values and preferences
  - When vulnerable, one or more of the elements of informed consent could be eroded – participate in research as a consequence of coercion and / or lack of understanding.
- \*Kipnis
  - *“... in the minds of many investigators the paradigmatic research subject remains more or less a mature, respectable, moderately well-educated, clear thinking, literate, self-supporting US citizen in good standing – that is, a man who could understand a 12-page consent form and act intelligently on the basis of its contents.”*
- This description - far cry from typical research participant in Africa where levels of literacy are low and poverty rife. Yet, in collaborative international research, consent forms presented to the Research Ethics Committees for review and approval are often those designed for the literate US citizen.

\*Kipnis K. Vulnerability in Research Subjects: A Bioethical Taxonomy. Commissioned Paper. In Ethical and Policy Issues in Research Involving Human Research Participants. Bethesda, MD: National Bioethics Advisory Commission. 2001

- Vulnerability associated with strong potential for exploitation.
- \*Resnik - three basic elements, at least one of which is requisite for exploitation
  - harm, disrespect and injustice
  - In practice, elements usually not present in isolation but often overlap and interact.
- Operational level, exploitation explained as the sum total of risks and harms with risks referring to the possibility of harm and harm referring to actual injury or damage.
  - Exploitation would result where, despite the risk of harm being recognised, the risky action is embarked upon with resultant harms.

\*Resnick D.B. Exploitation in Biomedical Research. Theoretical Medicine and Bioethics. 2003; 24: 233-259.

- Usually four:
  - Physical
  - Psychological
  - Social
  - Economic.
- These are exacerbated where participants are vulnerable.

- **UNESCO** two fundamental categories:
  - special disabilities, disease & limitations imposed by stages of human life
  - social, political and environmental determinants.
- **Kipnis** proposes a bioethical taxonomy with six types of vulnerability - distinguished by a positive response to a unique question.
  - cognitive, juridic, deferential, medical, allocational and infrastructural.

*Vulnerability exists as a broad spectrum, rather than a simple present / absent dichotomy, - possible to identify individuals / groups that are particularly vulnerable in research. Two sources of vulnerability at a conceptual level :*

- while often appearing independently, may coexist and are sometimes interrelated
- Intrinsic - due to internal qualities of individuals themselves, e.g., medical illnesses, mental disabilities and extremes of age.
- extrinsic, as a result of external circumstances, e.g., social



# Social Vulnerability

- Usually involves groups:
  - Stereotyping
  - Discrimination
  - Stigmatization
  - Social victimization

- **UNAIDS / SA DoH Guidelines:**
  - limited economic development
  - inadequate protection of human rights & discrimination on basis of health status
  - inadequate community / cultural experience with understanding of scientific research
  - limited availability of health care & treatment options
  - limited ability of individuals in community to provide informed consent

- **CIOMS 2002:**
  - “... *substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other necessities, or being a junior or subordinate member of a hierarchical group.*”
- **Ethical justification**
  - Couldn’t be carried out as well with non-vulnerable persons
  - Problem related to vulnerability
  - Participants and class will have reasonable availability to products
  - Risks without health benefits will not be greater than routine unless authorized
  - Supplemental consent when needed

- **CIOMS 2002:**

- *“Research in certain fields ... May present risks to the interests of communities, societies, or racially or ethnically defined groups. Information might be published that could stigmatize a group or expose its members to discrimination ...”*
- *“Plans to conduct such research should be sensitive to such considerations, to the need to maintain confidentiality during and after the study,.. .”*

- **NBAC**

- *“Research that is designed to study a group or that retrospectively implicates a group may ...result in members of the group facing, among other things stigmatization & discrimination in insurance & employment whether or not they contributed samples to the study”*
- *“Social perceptions are pervasive and often insidious and can affect persons’ conceptions of certain groups. Thus investigators, IRB members, and research sponsors should be sensitive to such perceptions and their effects and allow members of such groups to participate in decision making and oversight processes. **Involving the community in the various stages of the research process, especially in study planning**, can be helpful in reducing stereotyping and stigmatization.”*

- **DoH : strengths** - protection of vulnerabilities provisions in most articles.
- Specific mention of vulnerability
  - 9. *“Some research populations are particularly vulnerable and need specific protections.”*
  - 17. *“ ... Involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a **reasonable likelihood** that this population or community stands to benefit from the results of the research .”*

- **DoH : some weaknesses**

- *“Reasonable likelihood”* - no guarantee to a level of benefits that is fair
- protections against group harms and community consultation to prevent social harms. art22 specific to community consultation for voluntary participation.
- Art 14 – no firm commitment to compensation for research related injury. *“The protocol should include information regarding ... provisions for treating and / or compensating subjects who are harmed as a ...”*
- art15 – RECs. No mention of competency for review and CPD
- No article on biobanks

# Thank You