

Identifying and Protecting Vulnerable Populations

University of South Florida
IRB Training

What are vulnerable populations?

- Any individual that due to conditions, either acute or chronic, who has his/her ability to make fully informed decisions for him/herself diminished can be considered vulnerable
- Any population that due to circumstances, may be vulnerable to coercion or undue influence to participate in research projects.

Federal Regulations

- **Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research**
- **Subpart C – Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects**
- **Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research**
- **Subpart D (FDA) - Additional Safeguards for Children in Clinical Trials**

Other Populations

- Vulnerability does not necessarily have to be limited to an entire population
- Vulnerability is not limited to a chronic situation
- Vulnerability can be induced by a unequal perception of power
- Vulnerability can be created by a need for services, assistance, or protection
- Vulnerability can be caused by cultural, ethnic, or religious beliefs

NBAC Categories of Vulnerability

- In August 2001, the National Bioethics Committee proposed the following six categories of vulnerability:
 1. Cognitive or Communicative Vulnerability
 2. Institutional Vulnerability
 3. Differential Vulnerability
 4. Medical Vulnerability
 5. Economic Vulnerability
 6. Social Vulnerability

Cognitive or Communicative Vulnerability

- Capacity-related cognitive vulnerability: lack ability to make decisions, such as: children , cognitively impaired
- Situational cognitive vulnerability: do not lack capacity but are in situation that do not allow them to exercise that ability: stressful emergencies
- Communicative vulnerability: non-English speaking subjects

Institutional Vulnerability

- These individuals have the capacity to make decisions but are subject to formal authority of others – they are subordinate to others.
- Examples include: prisoners, military personnel, college students.
- There is the risk that decision-making will not be truly voluntary, consequently increasing the risk that there will not be respect for the person.

Deferential Vulnerability

- Subordination here is not to formal authority but to an informal authority.
- Socially constructed: based on gender, race, class inequalities
- Inequalities of power and knowledge: doctor-patient relationship
- Subjective: elderly deferring decision to adult children

Medical Vulnerability

- Subjects who have serious medical conditions for which there is no satisfactory standard treatments are often drawn to research because they or their physicians believe it is the best alternative for them.
- It may be difficult for these participants to weigh the risks and potential benefits of associated with the research.
- Subjects may not understand the research.
- High potential for these subjects to be exploited.

Economic Vulnerability

- These subjects are disadvantaged in the distribution of social goods and services such as income, housing or health care.
- This heightens the risk that the potential benefits from participation in the research might constitute undue inducements to enroll and threatens the voluntary nature of choice.
- Offers of large amounts of money or access to free health care may induce participation in research against their better judgment.

Social Vulnerability

Social perception of groups (stereotyping)

- External genetic determinism & stigmatization
- Internal genetic determinism & stigmatization
- Public policy genetic determinism
- Disruption of the group's values
- Loss of status in the majority society
- Raised expectations that lead to disappointment
- Dignity harms
- Increased distrust of health care

Mentally Disabled Individuals

- They have problems with the ability to understand and recognize the consequences of their actions.
- **This limited capacity may be continuous or fluctuating depending on the disability.**
- **They may have limitations on voluntariness because they are institutionalized or hospitalized.**

Emergency Situations

- Persons in emergency conditions often have limitations to their capacity to understand and consent to research due to time constraints or hospitalization.
- Persons in emergency conditions may be traumatized or sedated which also limits their capacity and voluntariness.

Educationally Disadvantaged

- These subjects may be limited through illiteracy or their ability to understand the study.
- The possibility exists for undue influence and/or manipulation.
- It may be desirable to get the signature of a witness to the consent process.
- Subjects who do not understand a study should not be enrolled.

Individuals with Life Threatening Disease

- These subjects often have limitations on voluntariness and may have problems with capacity due to illness.
- They may accept very high risk in desperation for a cure – even with little or no prospect for direct benefit.
- They may consent to participate in a study because of a real or perceived belief that participation is necessary to receive continuing care from health care professionals.

Elderly/Aged Persons

- The elderly as a group are autonomous.
- However, they can be cognitively impaired or they may be institutionalized.
- Elderly persons may have hearing or vision problems and may require larger font in the consent form or be given more time for the study to be explained to them.

Decisionally Impaired Individuals

- These individuals suffer from many different conditions that potentially affect their ability to reason and make sound choices.
- The ability to provide initial or ongoing consent to research may be limited by a variety of problems associated with memory understanding, and reasoning.
- A proxy consent should be obtained with assent from the subject whenever possible.

Minorities

- The inclusion of minorities raises concerns about the selection of subjects and the possibility of special vulnerability.
- Inclusion of minorities in research ensures their equal share in the benefits of research.
- There is the possibility of stigmatizing a minority if the research has a negative bearing on the minority.
- Some minorities may have additional vulnerability because of immigration status.

Normal Volunteers

- Volunteers for whom no personal benefit can result from participation in research should be exposed to risks that have been minimized to the greatest extent possible.
- The principles involved are beneficence and respect for persons.
- Normal volunteers should be recruited through general announcements or advertisements rather than through individual solicitations to reduce coercion.

Students

- Students may feel coerced to participate in research in order to gain favor with faculty or administrators who have input into their grades or placement in graduate programs.
- Faculty should recruit subjects from notices posted in the school or department.
- When possible, faculty should not enroll students over whom they have influence on grades, recommendations, etc.

Medical Students & Residents

- Medical students at USF may be recruited for research only after approval has been granted from the College of Medicine Student Affairs Committee.
- Medical Residents at USF may be recruited for research only after approval has been granted from the College of Medicine Graduate Medical Education Committee.

Employees

- Employees may be subject to coercion or undue influence or possible breaches of confidentiality when recruited to research conducted by their supervisors.
- Employees research programs raise the possibility that a person's decision about participation will affect performance evaluations or job advancements.

International Research

- International research projects require compliance with both USF policies and the relevant laws of the host country.
- Additional safeguards in such research include everything from use of a translator if the researcher is not fluent in the language of the country to waiving the requirement for written consent if the customs of the country demand it.

Cadaver/Tissue/Organ-Donation

- When Research involving deceased persons involves information about living family members that is both identifiable and private, the living family members themselves are considered research subjects.
- In the case of organ donation, the donor would be considered a research subject prior to death.
- Research on deceased persons must be carried out in accordance with Florida law and/or applicable Federal regulations.

Vulnerable to What?

- **Physical Control** – vulnerable subjects have been physically forced to participate in research
- **Coercion** – The use of a credible threat of harm or force to control another person.
- **Undue Influence** – The misuse of a position of confidence or power to lead participants to make a decision they would not otherwise have made.
- **Manipulation** – Deliberate management of conditions or information in such a way as to lead participants to make a decision they would not otherwise have made.

Points to Consider for Research involving Vulnerable Populations

- Additional procedures that will be utilized to protect and respect subjects' rights
- Description of how subjects disadvantages will be accommodated (including language barriers) in terms of recruitment, informed consent, questions during research, early withdrawal and research procedures.
- Steps that will be taken to minimize the possibility of coercion or undue influence being imposed on the individual.

Points to Consider for Research involving Vulnerable Populations

- Additional protections that will be built into the research to ensure respect of these individuals' rights.
- Description of how sufficient opportunity will be provided to subjects for consideration of whether to take part in the research.
- Description of steps that will be taken to discuss the research in language understandable to the subject.

Points to Consider for Research involving Vulnerable Populations

- Eliminate exculpatory language (language that appears to release the PI and/or institution from obligation) in the informed consent and discussion of the research.
- Risks are reasonable in relation to the anticipated benefits.
- Justification for using institutionalized individuals vs. non-institutionalized individuals in the research.


Points to Consider for Research involving Vulnerable Populations

- If greater than minimal risk, the risk must be justified by the anticipated benefits and the importance of the knowledge to be gained.
- Description of recruitment strategies for obtaining a diverse study population.
- Provide information on any additional risks subjects might face as a result of the population being studied and/or the local research context.

Points to Consider for Research involving Vulnerable Populations

- Procedures (appropriate to the research and the subject population) for evaluating the mental status of prospective subject to determine whether they are capable of consenting.
- Plan for initial and continuing assessment of each participants capacity to provide informed consent for those with diminished capacity: mentally disabled, cognitive disabilities, decisional impairments.

Points to Consider for Research involving Vulnerable Populations

- Plan for obtaining assent from adults unable to consent.
 - When applicable, identify persons authorized to give legally valid consent on behalf of any individual judged incapable of consenting on their own behalf.
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References

- NBAC Report on “Ethical & Policy Issues in Research involving Human Participants”:
http://www.bioethics.gov/reports/past_commissions/nbac_human_part.pdf
- The Presidents Commission on Bioethics with links to former Presidential Commissions:
<http://www.bioethics.gov/>