

Vulnerable Populations and Human Subjects Review



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What is a vulnerable population?

- The Belmont Report:

Respect for persons – have the responsibility to protect those with a limited or compromised autonomy

- The Common Rule:

B – Pregnant women, fetuses or neonates

C – Prisoners

D – Children

HRPP Chapter 9.3 - Risks to Vulnerable Populations

In addition, the HRPP also lists the following populations as requiring, when appropriate, additional safeguards:

- Veterans
- Persons with mental disabilities or economical disadvantages
- Educationally disadvantaged persons
- Employees and Students
- Other Potentially Vulnerable populations

HRPP Chapter 9.3, cont.

Veterans

The VA considers veterans a potentially vulnerable population because:

- have a history of obeying orders and making sacrifices
- some may not have access to other health care
- may sometimes have emotional issues from active duty (PTSD)



The VA also considers handicapped persons as a vulnerable population

HRPP Chapter 9.3, cont.

- People who have mental disabilities:
 - May not be able to consent legally for themselves
 - Issues surrounding coercion and undue influence
- Economically disadvantaged people:
 - May be easily coerced with incentives (not considered by the IRB to be a benefit)
 - May not have access to health care otherwise



HRPP Chapter 9.3, cont.

Educationally Disadvantaged

- May have issues understanding the informed consent process
- Illiteracy may prevent them from doing surveys or from performing written instructions
- May not be apparent; therefore, the researcher needs to be aware of their subject's circumstances



General Requirement of Informed Consent (45 CFR 46.116)
“the information must be given to the subject/LAR in language understandable to the subject/LAR

Chapter 14 HRPP Manual

Employees and Stanford University Students

“While employees and students are not vulnerable subpopulations per se, they may perceive that they are under some pressure from their superior to agree to participate. PDs must provide a rationale for involvement of employees or students of Stanford University.”



Chapter 14 HRPP, cont.

“When students (and employees) are involved, the PD must explain:

- **How they will be protected from coercion and undue influence, and**
- **What alternatives to participation exist”**

(HRPP 14.4)

Research Policy Handbook 7.5

“By virtue of their dependent positions, employees or laboratory personnel (and students) represent a vulnerable population”



Laboratory Employees and Students as Research Subjects

Research Policy Handbook 7.5:

- Subjects render the same written informed consent
- Avoid even subtle coercion
- Studies involving ANY type of intervention should be considered research
- Compensation is allowed and should go to all subjects, but compensation for full-time and exempt academic staff may not be allowed



Other Potentially Vulnerable Populations

- The IRB is composed of people from many backgrounds; diversity is intentional
- Allows for the IRB to consider circumstances of the participant, for example:
 - women participating in research in San Francisco versus Afghanistan
 - sick or suffering people may be desperate



Considerations in Reviewing Research Involving Vulnerable Participants

The IRB considers the following elements of the research plan when reviewing research involving vulnerable participants:

- **Strategic issues**
 - inclusion and exclusion criteria, informed consent, coercion and undue influence; and confidentiality of data
- **Group characteristics**
 - economic, social, physical, and environmental conditions
- **Participant selection** to prevent over-selection or exclusion of certain participants

Considerations in Reviewing Research Involving Vulnerable Participants, cont.

- **Application** of state or local laws
- **Procedures** for assessing and ensuring participants' capacity, understanding, and informed consent or assent.
- Need for **additional safeguards** to protect potentially vulnerable populations

