

Vulnerable Populations

Research involving vulnerable populations – Who are they?

Certain groups are considered to be vulnerable to coercion or undue influence in a research setting. Their tolerance for risk may also be altered. These groups are:

- Pregnant women, fetuses and neonates
- Children under the age of 18
- Cognitively impaired
- Prisoners
- Employees and students
- Minorities



Other groups include non-English speaking persons, economically disadvantaged persons, terminally ill patients, and veterans.

Pregnant women, Fetuses and Neonates

- Special attention due to women's additional health concerns during pregnancy
- Purpose of the research must be to meet the health needs of the mother and/or fetus
- Avoid unnecessary risk to the fetus
- Fetal research may be in utero or ex utero
- Informed consent of the father may be required

Children

- Persons who have not yet attained the legal age of consent (in most US states – 18 yo)
- Special requirements for informed consent
- Children must actively assent to participate in the research (verbal or comparable to consent forms used by adults)
- Assent process varies depending on the child's age, maturity and psychological state
- Parental/ guardian consent (sometimes from both parents)

Minorities

- Inclusion of minorities in research is important to make the research relevant to the widest possible range of population groups
- Ensure that all persons receive an equal share of the benefits of the research
- Ensure that minorities do not bear a disproportionate burden

Cognatively Impaired

- Decisionally-impaired subjects under the influence of medications, alcohol, severe pain, degenerative diseases affecting the brain, or have disabling handicaps
- Must specifically address how an individual's capacity to give informed consent will be determined
- Decision-making capacity should be tested and documented
- Determine who may provide consent
- Re-consent if a person regains his/her ability to give consent

Prisoners

- Only research that is relevant to the lives of the prisoners
- Research must impact prisoners as a population
- There must be a prisoner representative or advocate on the IRB (e.g. former prisoner, prison psychologist, etc.)
- If a person becomes a prisoner during a study, notify the IRB immediately
- Prisoners can be paid, but no undue inducement
- Risks cannot be higher than acceptable risk for non-prisoners

Employees and Students

- Research findings could affect an employee's pay/ benefits/ promotion potential, and student's academic achievement and job placement
- Employees and students may be under some pressure from their superior to agree to participate
- Explain how they will be protected from coercion and undue influence
- Unions may encourage employees to participate
- Alternatives to research participation must be provided

Research in Schools

- Besides dealing with children who already are a special population, there are additional regulations about conducting research in schools.
- Regulations protect privacy of student records and parental consent must also be obtained. This can be difficult. The IRB may approve an opt-out in low risk cases (parents have to sign to remove the child from the study instead of signing to enroll them).
- Research with immediate, practical outcomes relating to education may be exempt from the requirement for permission. For example, research on learning after testing a new curriculum does not require parental permission.