

Vulnerable/Special Populations

Vulnerable subject populations such as children, prisoners, and pregnant women (covered in the subparts of the federal regulations for human subjects research (45CFR46), and special classes of subjects including students, employees, and cognitively impaired individuals who may be vulnerable in terms of their research participation. The Belmont principle of respect for persons is not upheld when subjects are unduly influenced; that is, when they are offered an “excessive, unwarranted, inappropriate, or improper reward” in an effort to secure their participation in a research study. (Just one of many possible examples is offering free health care to individuals with major medical problems and limited resources as an inducement to participate.) Such offers may lead individuals to participate in studies to which they would otherwise have strong objections based on risk tolerance and personal values or preferences. Coercion involves an “overt or implicit threat of harm or reprisal” in order to obtain compliance with a request to participate in research. Coercion occurs when someone is in a position to make potential subjects worse off if they don’t participate. This power imbalance may very well interfere with a potential subject’s capacity to choose or act voluntarily. For example, a provider might threaten to withdraw services unless a client participates in a study, or a student might enroll in a study due to fear of receiving a poor grade in a class. Coercion can also take more subtle forms, such as when workplace culture encourages staff participation in research, and those who decline may be seen as outsiders who are not committed to organizational goals. With regard to cognitive impairment, the primary issue is impaired consent capacity, which occurs along a continuum in a wide range of conditions and circumstances. Assessments of consent capacity should be tailored to the study population, risk level, and likelihood of involvement of persons with cognitive impairment.

Federally Defined Vulnerable Populations Include:

Children (Minor < 18 years), including Wards of the State
Human Fetuses
Neonates
Pregnant Women
Prisoners

Other types of Vulnerable/Special Populations May Include:

Decisionally/Cognitive Impaired
Economically or Educationally Disadvantaged
Elderly and/or Nursing home residents
Hearing/Visually Impaired
Homeless
Illiterate
Institutionalized
Mentally Ill or mentally disabled
Military Personnel, Students, or Employees that are subordinate to the author
Non-English Speaking
Non-US Citizens
Poor/uninsured
Terminally ill, Chronically Ill, or Hospitalized Patients