

Appendix 1. Definition of Vulnerable Populations⁹

Individuals may be considered vulnerable because they do not have the decision-making capacity to provide voluntary informed consent, as in the case of children or the cognitively impaired, or because of the situation they are in (such as, being incarcerated or institutionalized). The following examples of groups are often considered vulnerable populations or in need of additional protections or considerations in research:

Pregnant women, Human fetuses, Neonates, Prisoners, Children, Individuals with physical disabilities, Individuals with mental disabilities or cognitive impairments, Economically disadvantaged, Socially disadvantaged, Terminally ill or very sick, Racial or ethnic minorities, Institutionalized persons (for example, persons in correctional facilities, nursing homes, or mental health facilities)

These groups require additional consideration and/or protections. They can also be considered potentially vulnerable because they may not be able to make informed decisions for themselves, they may be in situations in which they can easily be manipulated, or they may be a convenient and readily available study population.

Historically, those who are vulnerable have subjected to the following four types of abuses in human research:

Physical Control	Subjects who are physically forced to participate in research. This represents a complete lack of voluntariness. When subjects have no choice about whether or not to participate in research, and are under the complete physical control of the researchers.
Coercion	The use of a credible threat of harm or force to control another person. This also represents a lack of voluntariness.
Undue Influence	The misuse of a position of confidence or power to lead or influence others to make a decision they would not otherwise make.
Manipulation	The deliberate design and management of conditions or information intended to lead subjects to make a decision they would not otherwise make. Examples of information manipulation are lying, withholding information, or exaggerating.

⁹ reference from CITI training module "Populations in Research Requiring Additional Considerations and/or Protections"