Towson University IRB Guidance on Vulnerable Populations in Research

How are Vulnerable Populations Defined?

The National Bioethics Advisory Committee, in its 2001 report, *Ethical and Policy Issues in Research Involving Human Participants,* noted that "vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research."

Folks may be identified at risk because they have difficulty providing **voluntary** informed consent; may be members of a population that have been or could be exploited in research settings; and/or experience increased possibility of physical harm to an assault on their respect, health or rights, including not getting fair consideration in resource allocation.

The following vulnerable populations are specifically protected within 45 Code of Federal Regulations 46 (also known as the Common Rule): (i) Children; (ii) individuals with impaired decision-making capacity; (iii) economically or educationally disadvantaged persons; and (iv) prisoners. The Common Rule also contains subparts that describe special protections for the following vulnerable populations: Subpart B - Pregnant Women, Fetuses, and Neonates; Subpart C – Prisoners; and Subpart D – Children.

The most recently updated CITI training, however, suggests that the Common Rule's approach to identifying research participants as vulnerable is too limited because it uses a group-based approach that does not consider situations in which a person might be vulnerable or give attention to when an individual has multiple sources of vulnerability. The National Bioethics Advisory Committee (NBAC, 2001) defines vulnerable subjects as persons who "have difficulty providing voluntary informed consent arising from limitations in decision-making capacity…or situational circumstances…or because they are especially at risk for exploitation." The table below describes the types of abuses to which research subjects may be vulnerable. These abuses range from least, at the top, to most, at the bottom, severe.

Types of Abuse	Explanation	Example
Manipulation	The deliberate design and management of conditions or information intended to lead subjects to make a decision they would not otherwise make. This includes lying about study information, withholding information, or exaggerating information	Studies involving deception or incomplete disclosure; therapeutic misconception – when research subjects mistakenly believe (or are led to believe) that clinical research is designed to benefit them in some way rather than to advance science
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	Studies in which PI's have a position of power over potential research subjects (i.e., faculty collecting data on their own students; physicians recruiting their own patients to participate in a clinical trial). Also subject to the therapeutic misconception.
Coercion	The use of a credible threat of harm or force to control another person.	Withholding benefits for non-participation
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 to participate in research and are under the complete physical control of the researchers	Prisoners; Fetuses and Neonates; Children; Institutionalized persons

NBAC lists five sources of vulnerability.

These sources of vulnerability, and the impact they have on affected individuals, is described in the table below.

Types of Vulnerability	Definition and Examples
Cognitive or Communicative Vulnerability	**Capacity-**related factors, where someone may lack the cognitive capacity to evaluate potential risks (e.g., young children or legal minors) **Situational** factors affect the ability to make informed decisions such as during an emergency, acute illness, etc. **Communicative**-related factors, where Individuals who have a limited ability to understand or communicate with researchers such as those who do not speak English, are unable to read or have speech impairments, individuals who are intoxicated
Institutional Vulnerability	In this case, individuals may have the cognitive capacity to consent but **may not be in a position to make a voluntary choice** due to risks associated with non-participation or due to undue influence. The vulnerability stems from formal hierarchies where the individual perceives that they do not have the right to make a decision for themselves. (e.g., prisoners; enlistees in the military)
Deferential Vulnerability	This vulnerability arises from **informal power imbalances** which can make individuals at risk of exploitation or coercion. Feelings of trust or perceived subservience make it difficult for potential participants to say "no" to research participation (e.g., doctor/patient; teacher/student; parent; child).
Medical Vulnerability	**Serious health conditions** for which there are no known effective treatments **End of life** if there is hope that an experimental treatment may extend life or reduce pain **Therapeutic misconception** when individuals inaccurately attribute therapeutic intent to research procedures
Economic Vulnerability	When participation in research offers the possibility of payment or access to healthcare, housing, transportation, or other services **that are not otherwise available** due to a lack of economic resources
Social Vulnerability	Undervalued or marginalized groups for whom potential risks and burdens are undervalued relative to potential benefits leading to the possibility of exploitation (e.g., prisoners; illegal immigrants; racial/ethnic minorities; sexual/gender minorities)

Note also that some groups may experience more than one source of vulnerability. For example, illegal immigrants are both socially and economically vulnerable. Prisoners from minoritized identities may suffer from institutional, social and possibly economic vulnerability. Given these sources of vulnerability, NBAC suggests the following groups, not covered by the Federal Regulations, for whom additional protections should be considered:

1. Individuals who are critically ill
2. Individuals who are terminally ill
3. Individuals for whom decision-making is impaired due to cognitive or situational factors
4. Individuals with physical disabilities or Impairments (e.g., sight or hearing impairment)
5. Individuals who are economically disadvantaged
6. Individuals who are socially marginalized (e.g., racial and ethnic minorities)
7. Individuals who are on the low end of a social hierarchy (e.g., college students; prisoners; employees; etc.)
8. Sexual and gender minorities
9. Individuals with uncertain immigration status
10. Individuals involved in illegal activities (negative public health consequences for the group if fear of exposure will prevent them from seeking health care)

Principal Investigators must discuss the extent to which the population under investigation is vulnerable due to one or more of the sources listed above. In making these decisions, the PI should consider the following questions:

- Is there a power differential between researchers and subjects?
- Are there potential excessive motivating factors for subjects
- Are there potential communication issues for subjects?
- Are there potential decisional issues for subjects?
- Is the recruitment process acceptable?
- Are advertisements acceptable?
- Are there economic issues that might affect the acceptability of payment arrangements?

In addition, the PI should speak to the extent to which anticipated risks of the research are in excess of what would ordinarily be experienced in the day-to-day lives of the population to which the findings will be generalized. For example, risk of coercion due to a power differential may not be a problem when a faculty member recruits students with whom they have no existing relationship (i.e., are not advisees; are not in their classroom) but that may become a risk, making potential participants vulnerable, if they want to recruit participants from their own classroom.

Questions IRB members should consider when reviewing protocols involving vulnerable populations include:

- Are there reasonable accommodations for subjects who may be disabled?
- Is information presented in an understandable and accessible manner?
- Do subjects comprehend the research details and their rights?
- Is the consent process conducive to voluntariness?
- Who is involved in the consent process?
- Can subjects consent for themselves?
- Do the vulnerabilities of the subjects require additional procedures of a research subject advocate?

In addition, PIs are motivated to assume that their populations are not vulnerable. As such, IRB members should also consider the extent to which the study population may be subject to one or more of the sources of vulnerability listed above.

Source:

Ethical and policy issues in research involving human participants: report and recommendations of the National Bioethics Advisory Commission. National Bioethics Advisory Commission. bioethicsarchive.georgetown.edu/nbac/human/overvol1.pdf. Published August 2001.