

“Vulnerable Subjects”

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Polit and Beck (2004) define vulnerable subjects as those who “may be incapable of giving informed consent (e.g. mentally retarded people) or may be at high risk of unintended side effects because of their circumstances (e.g. pregnant women) (p. 154).

Polit and Beck identify issues that need to be carefully considered with this group including:

- Informed consent
- Risk/benefit assessment
- Research procedures

The authors also note that research should be conducted only in the following circumstances:

- Risk is low and benefit is high, or
- No alternatives to the study are possible (study of pregnancy require pregnant women)

Vulnerable populations identified by the authors include:

- Children
 - Legally or ethically children are not competent to give informed consent
 - Informed consent must be obtained from the parent or guardian
 - Assent (agreement) from the child should be obtained if appropriate
 - If the child is able to understand, written informed consent should be obtained.
- Mentally or emotionally disabled individuals (senility, unconsciousness, etc.)
 - Legally or ethically cannot provide informed consent
 - Written consent should be obtained from the legal guardian
- Very ill or physically disabled individuals
 - The individual’s ability to give informed consent must be assessed
 - For individuals with certain disabilities, special steps must be undertaken. For example, if an individual is deaf or cannot read or write the consent process may need to be written out or read.
- Terminally ill individuals
 - The risk/benefit ratio must be considered because there is most likely not a benefit to the individual
 - Comfort must be considered
 - Special procedures must be followed if they are mentally or physically incapacitated.
- Institutionalized individuals
 - Extra precautions must be taken due to the possibility of feeling pressured to participate.
- Pregnant women
 - The fetus must also be considered
 - The purpose of the research must “meet the needs” of the pregnant woman (p. 155)
 - Minimal risk to the fetus and pregnant woman

A search in Medline using the OVID database was conducted from 1966 to present using the search headings “vulnerable populations” and “transplantation”. This search found 1270 articles on “vulnerable populations” and 242,089 on “transplantation”. When the key words were combined, 22 articles on vulnerable populations in transplantation were found with only 4 published in the last 5 years. These are listed below.

1. Wolfe WA. **Achieving equity in referrals for renal transplant evaluations with African-American patients: the role of nephrology social workers.** [Journal Article] *Social Work in Health Care*. 37(3):75-87, 2003.

2. Delmonico FL. Scheper-Hughes N. **Why we should not pay for human organs.** [Journal Article] *The National Catholic Bioethics Quarterly*. 2(3):381-9, 2002 Autumn.

3. de Castro LD. **Human organs from prisoners: kidneys for life.** [Journal Article] *Journal of Medical Ethics*. 29(3):171-5, 2003 Jun.

4. Gillett GR. **Unnecessary holes in the head.** [Journal Article] *Irb: a Review of Human Subjects Research*. 23(6):1-6, 2001 Nov-Dec.

Two non-transplant articles that may be interesting for you to review involving vulnerable populations include:

1. Goddard, L, & Jordan, L. (1998). Changing attitudes about person with disabilities: Effects of a simulation. *Journal of Neuroscience Nursing*, 30(5), 307-313.
2. McNeely, E., & Clements, S. (1994). Recruitment and retention of the older adult into research studies. *Journal of Neuroscience Nursing*, 26(1), 57-61.

Reference

Polit, D. F., & Beck, C. T. (2004). *Nursing research: Principles and methods* (7th ed.). Philadelphia, PA: Lippincott, Williams, & Wilkins.