Vulnerable Populations: who are they?

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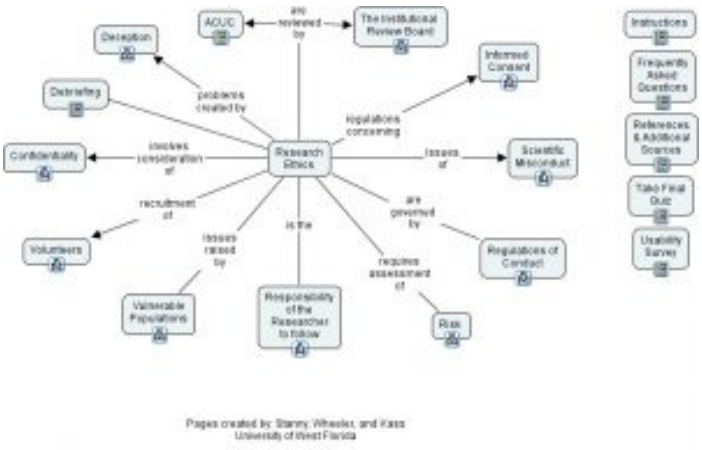
This is the fourth in a series of articles about medical ethics. Our previous posts in this series included the basics of medical ethics, the difference between utilitarianism and deontology, and the Belmont Report.

Today we will review vulnerable populations. The idea of vulnerable populations falls under the ethical construct of respect for persons. Remember that this principle is about autonomy, where an autonomous individual is capable of making decisions about their personal goals and beliefs. In research, this means that participants of research voluntarily agree to participate and have enough information provided to them for them to make that decision reasonably. Individuals who lack this capacity, either fully or partially, are considered vulnerable because they may not have the maturity or capacity to make an informed decision.



Vulnerable groups include children, the poor, elderly people, homeless, the mentally ill, and racial or ethnic minorities. It can also include the uninsured or uneducated. In the case of prisoners, soldiers, or other

institutionalized individuals, they may be under the influence of subtle coercion or undue influence. Vulnerabilities may be classified as physical, psychological, or social according to the American Journal of Managed Care.

The FDA regulates clinical research in certain vulnerable groups specifically. Children, prisoners, pregnant women, mentally or physically handicapped or disabled persons, and economically or educationally disadvantaged persons are specifically addressed in the US Code of Federal Regulations Title 21, Part 56.111, Criteria for IRB approval of research, and under Health and Human Services regulations, Title 45, Part 46.201, Subpart B—Protections for pregnant women, human fetuses, and neonates involved in research, Subpart C—Protections pertaining to biomedical and behavioral research involving prisoners, and Subpart D—Protections for children involved in research.

With approximately 1% of US residents incarcerated as of 2013, the issue of research ethics in this population is an important one. A 2002 report indicated that despite the requirements of 45 CFR 46, Subpart C that curtails most research on prisoners, the majority of this type of research occurs outside the purview of federal regulations and without review or approval by an IRB. Little research is conducted in prisons as medical clinical trials or biomedical studies, however, most studies were social, behavioral, program evaluations, or record review in nature.

Using prisoners as an example, we'd like to remind you that the number of vulnerable individuals is growing in the US. The issues surrounding medical care, and specifically research in these populations continue to challenge bioethicists and clinical researchers. So, continue to ask questions during protocol and informed consent development, while consenting potential participants, and while reviewing medical records to be aware of patients who may fit a vulnerable description.

Thank you for tuning into HCC's ethics series.