

Guidance and Procedures Number: 20

Title: Special Considerations for Projects Involving Vulnerable Populations

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I. Introduction

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, fetuses, and mentally disabled persons, handicapped persons, or economically or educationally disadvantaged persons (45 CFR 46.111(b) and 21 CFR 56.111(b)). The regulations include specific provisions for research involving fetuses, pregnant women, and neonates (45 CFR 46, Subpart B), prisoners (45 CFR 46, Subpart C), and children (45 CFR 46, Subpart D and 21 CFR 50 Subpart D). The federal regulations do not include specific requirements for the protections of other vulnerable subject populations, such as the elderly or terminally ill or economically, educationally or socially disadvantaged subjects. When a research study involves vulnerable populations for which specific federal guidance is not provided, the IRB will evaluate the need for additional protections on a case-by-case basis.

When an IRB reviews research involving a vulnerable category of subjects, it will include one or more individuals qualified to represent that group, either through personal experience or experience working with that population. The staff of each IRB are responsible for ensuring that appropriate membership is present for such reviews.

II. Issues to Consider in Research Involving Vulnerable Subjects

- A. The IRBs will closely examine research involving vulnerable subject populations to ensure that the selection of subjects is equitable and free of coercion.
- B. The IRBs will assess whether extra precautions should be taken to safeguard the rights and welfare of vulnerable subject populations who might be susceptible to coercion or undue influence.
- C. When vulnerable populations are involved in research, the appropriateness of involving them should itself be assessed. A number of factors are involved in such judgments, including the nature and degree of risk, the type of vulnerability of the particular population involved, the nature and level of the anticipated benefits and the availability of alternatives.
- D. The IRBs will ensure that vulnerable subjects are not involved in research solely because they are readily available in settings where research is conducted.
- E. The IRBs will carefully consider the risks and benefits of the research with regard to the vulnerable subjects' specific situation.

Regulations:

21 CFR 50, Subpart D

21 CFR 56.111

45 CFR 46.111

45 CFR 46, Subpart B

45 CFR 46, Subpart C

45 CFR 46, Subpart D

References:

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979. <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook (1993)*, Chapter 6, Special Classes of Subjects". http://hhs.gov/ohrp/irb/irb_chapter6.htm