Inclusion of Vulnerable Populations in Research Activities

Vulnerable Populations and Exempt Research

Special Consideration for Projects Involving Vulnerable Populations

Inclusion of Vulnerable Populations in Research Activities

When some or all of the subjects that will be enrolled in a research study are likely to be vulnerable to coercion or undue influence, such as pregnant women, prisoners, children, and cognitively impaired adults, additional safeguards must be included in the study to protect the rights and welfare of these subjects.

In addition to the responsibilities prescribed for the IRB under 45 CFR Part 46, Subpart A, the IRB shall follow special procedures with respect to prisoners, and children as specified in Subparts C and D. Inclusion of other vulnerable populations as research subjects is considered by the IRB.

There are a number of research populations described in the Federal regulations as "vulnerable" or that require additional consideration or protection. "Vulnerable" or "special" classes of subjects include:

1. pregnant women, human fetuses and neonates,
2. prisoners,
3. children,
4. cognitively impaired persons
5. students and employees
6. minorities
7. economically and/or educationally disadvantaged
8. AIDS/HIV+ subjects.
9. terminally ill subjects
In addition, the regulations outline specific provisions for research involving:

- fetuses,
- pregnant women, and in vitro fertilization
- prisoners, and
- children.

**Vulnerable Populations and Exempt Research**

Due to the vulnerable nature of the population, the exemptions in 45 CFR 46.101(b) do not apply to certain types of research involving children and prisoners, Subparts C and D.

Specifically, the exemption in 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

In addition, exemption from IRB review should be utilized conservatively when applied to research involving special classes of subjects who are not be defined by regulation as vulnerable.

**Special Consideration for Projects Involving Vulnerable Populations**

In reviewing these research projects, the IRB determines if the inclusion of the vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to each population.

During its review, the IRB must determine which of the following categories the research would involve:

- the research does not involve more than minimal risk to the subject;
- the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal;
- the research involves greater than minimal risk with no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition; or
- research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the subject.

Requests for approval of any research that exposes vulnerable populations to risks that do not meet one of the above criteria must be submitted to the United States Secretary of Health and Human Services for review and approval.

Special protections are essential to guide research involving vulnerable persons. In order to review projects involving the use of vulnerable populations as specified in 45 CFR 46, an IRB must have present at its meeting an advocate for these subjects.
The mere presence of the appearance of vulnerability should not lead to a presumption that a person is incapable of making a decision regarding participation in research and of giving valid informed consent. Yet sometimes these conditions do impair the decision-making capacity required to give a valid informed consent, raising ethical concerns about the vulnerability of persons in such conditions in research.