Guidelines for Review of Research Involving Vulnerable Populations Not Covered by Subparts B, C, and D

Purpose

This policy will address and provide guidance concerning vulnerable populations not covered by Subparts B, C, and D.

Policy

Boston Children's Hospital applies subparts B, C, and D to federally funded research and research under the jurisdiction of the FDA. Policies for these populations are covered separately, see:

- ***Pregnant Women, Human Fetuses, and Neonates***
- ***Incarcerated Youth and Prisoners***
- ***Children***
- ***Wards of State***

Other groups such as the socially, educationally, and economically disadvantaged, elderly, and terminally ill do not have specific regulatory protections. However, when research involves one of these other groups the IRB will evaluate the need for additional protections on a protocol-by-protocol basis.

When the Boston Children's Hospital 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 the populations. In addition, the IRB will ascertain that additional safeguards to protect the rights and welfare of any vulnerable subjects will be included in the research.

Adults with questionable decision-making capabilities are addressed in a separate policy, see ***Research Involving Individuals with Decisional Impairment***.

Vulnerable Subjects

For research involving participants who are vulnerable to coercion and undue influence and who can give consent, the IRB will apply the following additional criteria:

1. The inclusion of the vulnerable population is acceptable because either:
    a. The inclusion of the vulnerable population is likely because of the setting of the research, and the setting is not designed to target vulnerable participants; or

   b. The research is designed for a disease or condition relevant to the vulnerable population under study.
2. The research does not target vulnerable participants as a matter of convenience.
3. The recruitment process includes additional safeguards to minimize coercion and undue influence.
4. The IRB will consider the nature of the risks, the type of vulnerability, and the nature and level of anticipated benefit in addition to the availability of alternatives.
5. The consent process includes additional safeguards to minimize coercion and undue influence.
6. The financial payment (if any) to participants is not coercive or unduly influential.

Related Content

IRB Policies

Children

Incarcerated Youth and Prisoners

Pregnant Women, Fetuses, Neonates

Research Involving Individuals with Decisional Impairment

Wards of State

Document Attributes

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