



Guidelines for Review of Research Involving Vulnerable Populations

Policy

When the 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 be certain that additional safeguards to protect the rights and welfare of any vulnerable subjects will be included in the research, Special issues of vulnerability to coercion or undue influence will be carefully considered. Children's Hospital applies subparts B, C to federally funded research and part D to federally funded research and research under the jurisdiction of the FDA. Guidelines for these populations are covered separately Other groups such as the socially, educationally and economically disadvantaged, elderly, and terminally ill do not have specific regulatory protections. When a research involves one of these other groups the IRB will evaluate the need for extra protections on a protocol by protocol basis. This policy will address vulnerable populations not covered by Subparts B, C, and D and there adults with questionable decision making capabilities

Vulnerable Subjects

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

- The inclusion of the vulnerable population is acceptable because either:
 - 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
 - The research is designed for a disease or condition relevant to the vulnerable population under study
- The research does not target vulnerable participants as a matter of convenience.
- The recruitment process includes additional safeguards to minimize coercion and undue influence.
- 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
- The consent process includes additional safeguards to minimize coercion and undue influence.
- The financial payment (if any) to participants is not coercive or unduly influential

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