Special Categories of Research - Participants Who May Be Vulnerable to Coercion or Undue Influence

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic IRB is the IRB of Record

Purpose

This document describes the requirements for research proposals that include human subjects who may be considered vulnerable to coercion or undue influence.

Policy

It is the policy of the Mayo Clinic Human Research Protection Program (HRPP) and the Mayo Clinic IRB (Institutional Review Board) to ensure that additional safeguards have been included in proposed research to protect the rights and welfare of subjects who may be vulnerable to coercion or undue influence.

Investigator Responsibilities

- The Investigator will specify the target population for the research in their IRB submission and provide justification for inclusion of prospective subjects who may be vulnerable to coercion or undue influence.
- The Investigator will obtain informed consent from subjects. See IRB document *Informed Consent and the Research Subject*.

IRB Responsibilities

- The IRB will review the proposed research, taking into consideration the additional requirements for inclusion of any potential subjects who may be vulnerable to coercion or undue influence as set forth in IRB document *IRB Initial Approval of Research*.
- When the researcher plans to approach adults who may lack the capacity to consent, the IRB will evaluate and document in its determination whether:
    - The proposed plan for the assessment of the capacity to consent is adequate.
    - Assent of the participants is a requirement, and, if so, whether the plan for assent is adequate.
- The IRB will document its assessment of the appropriateness and adequacy of additional protections for vulnerable populations.

Vulnerable Populations

Vulnerable populations include (but not limited to): pregnant women, prisoners, children, cognitively impaired persons, students and employees, minorities, economically disadvantaged persons, educationally disadvantaged persons, cognitively impaired adults, Native Americans, and Non-English speakers.

Related Documents

IRB Initial Approval of Research

Informed Consent and the Research Subject

Special Categories of Research - Children

Special Categories of Research - Prisoners

Special Categories of Research - Pregnant Women, Human Fetuses, and Neonates

References

45 CFR 46 - Protection of Human Subjects

Effective Date

August 4, 2015