

Special Categories of Research: Vulnerable Human Subjects Policy

Scope

Applies to Mayo Clinic Human Research Protection Program (HRPP) personnel when Mayo Clinic is the Reviewing Institutional Review Board (IRB) for research involving vulnerable human subjects.

Purpose

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 and to comply with regulatory requirements. This policy describes the requirements for research proposals that include vulnerable human subjects like ethnic or racial minorities, non-English speakers, economically disadvantaged, adults with diminished capacity, etc.

Policy

• Investigator Responsibilities

- The Investigator will specify the target population for the research in their IRB submission and provide justification and additional protections for inclusion of prospective subjects who may be vulnerable to coercion or undue influence.
- The Investigator will obtain legally effective informed consent from subjects, or if approved by the IRB of record, their legally authorized representative(s). Refer to the Policy: [Informed Consent and the Research Subject Policy](#).
- The Investigator will assess capacity to consent to research. Refer to [Informed Consent and Assessment of Capacity to Consent to Research Policy](#).

• 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 [Institutional Review Board \(IRB Initial Approval of Research Policy\)](#).
- When the researcher plans to approach adults who may lack the capacity to consent, the IRB will evaluate and document in its determination if:
 - The proposed plan for the assessment of the capacity to consent is adequate.
 - Assent of the participants is a requirement, and, if so, the plan for assent is adequate.
- The IRB will document its assessment of the appropriateness and adequacy of additional protections for vulnerable populations.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

[Informed Consent and Assessment of Capacity to Consent to Research Policy](#)

[Informed Consent and the Research Subject Policy](#)

[Institutional Review Board \(IRB\) Initial Approval of Research Policy](#)

[Special Categories of Research - Pregnant Women, Human Fetuses, and Neonates Policy](#)

[Special Categories of Research: Children Policy](#)

[Special Categories of Research: Prisoners Policy](#)

Definitions

Vulnerable Human Subjects: Vulnerable populations may include (but are not limited to): individuals who are pregnant; prisoners; individuals who have been involuntarily committed to a medical facility; children; subordinates such as students, trainees, and employees; individuals who are economically or educationally disadvantaged; individuals who have a language barrier; individuals with a cognitive disability; and individuals with an illness for which all standard treatment options have been exhausted. Federal regulations state that “when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects”. (45 CFR 46.111[b] FDA regulations expressly identify "mentally disabled persons" as a vulnerable category of subjects in clinical investigations for which IRBs may need to assume increased responsibilities per 21 CFR 56.107[a] and 56.111[b]).

References

[45 CFR 46 - Protection of Human Subjects](#)

[21 CFR Institutional Review Boards](#)

Owner

[Michelle Daiss](#) on behalf of Mayo Clinic Human Research Protection Program

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Revision History

Date	Synopsis of Change
01/26/2024	Scheduled Review
11/10/2023	Updated Owner and Contacts. Minor edits.
03/08/2021	Updated Owner and Contact. Updated References and definition. Minor edits throughout.
08/21/2018	Scheduled review, no changes at this time due to AAHRPP Accreditation Cycle. Removed 'Approved by' section -- no longer on template. Corrected Angie's last name.
08/24/2016	Updated to current template per the Policy Governance and Standardization Project, change title to follow title guidelines, aligned text to indicate vulnerable human subjects throughout the document, added who (vulnerable human subjects) to scope and changed to paragraph structure, defined Institutional Review Board as IRB and used IRB consistently throughout the document, hyperlinked vulnerable human subjects in the scope to the definition and minor editorial changes for clarity.

Content Information Stamp

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Applicable Sites

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Arizona

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Florida

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