Special Categories of Research - Vulnerable Human Subjects Policy

Scope
Mayo Clinic Human Research Protection Program
Research for which Mayo Clinic is the IRB of Record

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

Policy
- The Mayo Clinic Human Research Protection Program (HRPP) and the Mayo Clinic Institutional Review Board (IRB) 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 legally effective informed consent from subjects, or if approved by the IRB of record, their legally authorized representative(s). See IRB document Informed Consent and the Research Subject.
  
  - The Investigator will assess capacity to consent to research. See IRB document Informed Consent and Assessment of Capacity to Consent to Research

- 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.
Definitions
Vulnerable human subjects include (but are 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.

References
45 CFR 46 - Protection of Human Subjects

Owner
Pamela Kwon on behalf of Mayo Clinic Human Research Protection Program

Contact
Michelle Daiss; Angela Patterson

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
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<tbody>
<tr>
<td>08/21/2018</td>
<td>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.</td>
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<tr>
<td>08/24/2016</td>
<td>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.</td>
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