

4.1 Additional Protections for Vulnerable Populations

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for additional protections for vulnerable populations.

2.0 Policy

- **2.1.** It is the policy of the Organization that vulnerable populations will be afforded additional protections, in accordance with the ethical principles described in the Belmont Report, and the requirements of 45 CFR 46.111(b) and 21 CFR 56.111(b).
 - **2.2.** It is the policy of the Organization that the requirements for special protections specified under HHS regulations at 45 CFR 46 Subpart B (pregnant women, human fetuses and neonates of uncertain viability or non-viable), Subpart C (prisoners), and Subpart D (children) will be applied for research funded by any of the Common Rule agencies or departments.
 - **2.3.** It is the policy of the Organization that equivalent protections will be provided for the vulnerable populations described above who are participating in research not funded by any of the Common Rule agencies or departments. Equivalent protections will be based upon the ethical principles in the Belmont Report, and the requirements in 45 CFR 46, Subpart B, C, and D will be applied to the greatest extent possible in consideration of the nature of the research.
 - **2.4.** It is the policy of the Organization that the additional safeguards for children in clinical investigations under FDA regulations at 21 CFR 50 Subpart D will be applied for research regulated by the FDA.
 - **2.5.** It is the policy of the Organization that additional protections will be provided for other vulnerable populations including, but not limited to, decisionally-impaired persons, terminally ill, or economically or educationally disadvantaged persons. In these situations, the IRB, in consultation with the PI, will determine the appropriate methods to protect the rights and welfare of the individuals in consideration of the principles of the Belmont Report, the nature of the research, and other factors determining vulnerability.
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3.0 Definition

- **3.1. *Vulnerable Persons*** are defined as individuals or groups of individuals "with diminished autonomy" (National Commission, 1979) or as individuals or groups of individuals who "have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity ... or situational circumstances ..., or because they are especially at risk for exploitation" (National Bioethics Advisory Committee, 2001). Within any group of vulnerable subjects, individuals may have different levels of vulnerability based on the level of capacity, circumstance, or condition. In addition, "vulnerability is sensitive to context, and individuals may be vulnerable in one situation but not in another" (National Bioethics Advisory Committee, 2001).
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4.0 Categories of Vulnerability

- **4.1.** Broadly, vulnerabilities in the context of research may be considered to fall into one or more of the following types:
 - **4.1.1. Cognitive or Communicative:** diminished capacity to understand or communicate.
 - **4.1.2. Institutional:** subject to the formal authority of others.
 - **4.1.3. Deferential:** informal subordination to others (gender, race or class inequalities; inequalities of power and knowledge).
 - **4.1.4. Medical:** serious health conditions.
 - **4.1.5. Economic and/or Social - disadvantaged** in the distribution of social goods and services, or belonging to an undervalued group.
- **4.2.** Vulnerable person may also be considered as belonging to certain groups or populations. Though useful, categorization in this manner needs to consider context and situation. Groups include, but are not limited to:
 - **4.2.1.** Pregnant women (Subpart B) (see [HRPP policy 4.2](#)).
 - **4.2.2.** Fetuses and neonates (Subpart B) (see [HRPP policy 4.2](#)).
 - **4.2.3.** Prisoners (Subpart C) (see [HRPP policy 4.3](#)).
 - **4.2.4.** Children (Subpart D) (see [HRPP policy 4.4](#)).
 - **4.2.5.** Decisionally impaired (see [HRPP policy 4.6](#)).

- 4.2.6. Critically ill persons
- 4.2.7. Terminally ill persons
- 4.2.8. Blind or deaf persons, or persons with other disabilities
- 4.2.9. Economically or socially disadvantaged persons
- 4.2.10. Educationally disadvantaged persons
- 4.2.11. Employees and students (see [HRPP policy 4.7](#)).
- 4.2.12. Non-English speaking persons

5.0 Additional Protections for Vulnerable Populations

- 5.1. Investigators must consider whether subjects to be enrolled in their research might be vulnerable, and if so, what additional protections might be appropriate to provide additional protections.

In making the latter determination, investigators should consider:

- 5.1.1. Is inclusion of the vulnerable person or population necessary? That is, could the aims of the research be accomplished by enrolling persons or a population that is not (or less) vulnerable?

Note: Investigators should be aware that there are competing ethical imperative related to enrollment of vulnerable persons. The Belmont Principle of Respect for Persons requires that investigators protect those with limited autonomy (even to the extent of excluding them from the research); however, the Belmont Principles of Beneficence and Justice require that researchers provide the benefit of research, and distribute those benefits fairly.

Investigators should also be cognizant of the risks of not including certain populations in research. For example, considering children as research subjects, the National commission noted “The argument in favor of conducting research involving children rests on ... the consequences of not conducting research involving children in those instances. Such consequences might include the perpetuation of harmful practices, the introduction of untested practices, and the failure to develop new treatments ...” (National Commission: Research Involving Children. Report and Recommendations, 1977; page 21).

- 5.1.2. If so, then are protections afforded to subjects adequate?
 - 5.1.2.1. Do prospective subjects have difficulty providing voluntary, informed consent? Are condition for informed consent satisfied? (Is information presented in an understandable manner? Do subjects comprehend the details of the research and their rights as research subjects? Is the process of consent conducive to true voluntariness?)
 - 5.1.2.2. Are prospective subjects at risk for exploitation?
- 5.2. Specific additional protections that might be considered include (but are not limited to):
 - 5.2.1. The use of an extended consent process.
 - 5.2.2. The use of a consent monitor.
 - 5.2.3. Appointment of a subject advocate.
 - 5.2.4. Involvement of the subject’s family and/or friends.
 - 5.2.5. The requirement for re-consenting of subjects/LARs.
 - 5.2.6. Limits placed on risk.
 - 5.2.7. Increased monitoring of the research through use of a Data Safety Monitoring Board or other mechanisms.
 - 5.2.8. More stringent withdrawal criteria.
 - 5.2.9. Longer study follow-up.
 - 5.2.10. Exclusion from participating in the research.

6.0 Investigator and IRB Procedures Regarding Inclusion of Vulnerable Persons or Populations

- 6.1. The investigator must identify whether research will include any population which is directly subject to the additional protections in 45 CFR 46 subpart B, C or D, or 21 CFR 56 subpart D
- 6.2. The investigator must identify whether subject eligibility criteria will specifically target other potentially vulnerable populations, or whether there is a high likelihood that a sizable number of subjects will come from a vulnerable population.

Note: the intent here is to identify research proposals for which it would be reasonable to have additional protections in place prior to enrollment. The intent is not to identify situations when a vulnerable person would incidentally be enrolled. In the latter case, it is expected that the investigator would identify that person and take appropriate actions.

- 6.3. The investigator must specifically describe additional protections for persons or populations identified in sections 7.1 and 7.2.
- 6.4. The IRB will consider whether inclusion of vulnerable subjects or populations is appropriate, and whether the additional protections proposed as adequate, as required in [HRPP policy 2.5](#) (Criteria for Approval).
- 6.5. The IRB will consider whether the inclusion of vulnerable subjects satisfies the requirements of 45 CFR 46 subpart B, C or D, or 21 CFR 56 subpart D, and of [HRPP policies 4.2](#) (Research Involving Pregnant Women, Human Fetuses, and Neonates – Nonviable or of Uncertain Viability), [4.3](#) (Research Involving Prisoners), [4.4](#) (Research Involving Children), [4.6](#) (Research Involving Subjects with Impaired Decision Making Capacity) and/or [4.7](#) (Research Involving Employees and Students).

- **6.6.** If the IRB reviews and approves a protocol which does not involve vulnerable subjects but a subject, after enrollment, becomes vulnerable (for example, by being incarcerated, or becoming pregnant or homeless), the PI must notify the IRB and revise the IRB Application as applicable. The IRB will review the submission in order to determine that the vulnerable subject(s) has appropriate additional protections.
 - **6.6.1.** Subjects participating in federally funded research who fall under the requirements of Subparts B, C, or D must be withdrawn from the study unless their continued participation is in compliance with that Subpart.
 - **6.6.2.** The IRB determinations regarding inclusion of pregnant women, prisoners, and children will be documented in accordance with [HRPP policies 2.2](#) (Full IRB Review), [2.3](#) (Expedited IRB Review), [4.2](#) (Research Involving Pregnant Women, Human Fetuses, and Neonates-Nonviable or of Uncertain Viability), [4.3](#) (Research Involving Prisoners), and/or [4.4](#) (Research Involving Children).
 - **6.6.3** The IRB determinations regarding inclusion of other vulnerable populations will be documented in accordance with [HRPP policies 2.2](#) (Full IRB Review) and [2.3](#) (Expedited Review).
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