PROTECTING VULNERABLE POPULATIONS IN HUMAN SUBJECTS RESEARCH

POLICY

If individuals may be vulnerable to coercion or undue influence to participate in a research study, additional protections must be established to safeguard their rights and welfare. Institutional Review Board (IRB) approval of the research will not be granted until all appropriate additional protections have been assured [see Human Research Protection Program (HRPP) Procedure 308 IRB Review of Research Involving Pregnant Women, Fetuses and Nonviable Neonates, HRPP Procedure 331 IRB Review of Research Involving Prisoners, HRPP Procedure 332 IRB Review of Research Involving Minors, HRPP Procedure 333 IRB Review of Research Involving Cognitively Impaired Individuals and HRPP Procedure 334 IRB Review of Research Involving Other Vulnerable Populations].

DEFINITIONS

Groups or individuals who may not be fully capable of deliberation and the ability to express opinions or choices because of circumstances, illness, or incapacitation are considered vulnerable. Populations that are presumed to be vulnerable to coercion or undue influence include the following groups:

- Pregnant women, fetuses and nonviable neonates. Viable neonates are considered to be Minors,
- Prisoners,
- Minors,
- Cognitively impaired individuals, and
- Others who may be vulnerable to undue influence including educational or economic or cultural constraints and unequal superior/subordinate relationships

ASSURING ADDITIONAL PROTECTIONS

HRPP staff will identify any vulnerable populations during administrative pre-review and ensure that all pertinent additional documents are provided by the researcher, including but not limited to any appropriate checklist, special consent document, consent comprehension tool, etc. HRPP staff will assign review of the submission to one or more IRB members who are knowledgeable about the unique needs of the identified vulnerable population and the appropriate additional protections that should be provided (see HRPP Procedure 301 Administrative Pre-Review of Research Submissions, Initial Determination of Review Type, and Assignment of Reviewers).
The assigned IRB member(s) will review the research plan and all additional documents to assure that appropriate additional protections are included. Protections should enhance a potential participant’s ability to understand the research and make a reasoned decision about whether or not to participate. A consultant may provide additional review if requested by the IRB (see HRPP Policy III.01 Review of Human Subjects Research by the IRB and HRPP Procedure 305 Inviting Consultants to Review IRB Protocol Documents).

If the research proposal requires review at a convened IRB meeting, the IRB Chair or designee will ensure that one or more IRB members who are knowledgeable about the needs of the identified vulnerable population will be present at the meeting or that a non-member consultant's review report is available at the meeting when the study is discussed.

Methods used to enhance participant understanding of the research prior to obtaining informed consent must be described (see HRPP Policy II.01 Obtaining Informed Consent in Human Subjects Research and HRPP Procedure 201 Writing an Informed Consent Document for Human Subjects Research.

For Veterans Affairs Medical Center (VAMC) research, additional protections or restrictions may apply, as specified in the Veterans Health Administration (VHA) Handbook 1200.5, Appendix D.

IRB meeting minutes and/or records will document specific findings in accordance with VAMC requirements. Where relevant, the IRB must document why it considers an individual or population to be vulnerable, and that adequate safeguards have been included in the study to protect the rights and welfare of participants who are likely to be vulnerable. Individuals or populations that might be temporarily or permanently vulnerable include, but are not limited to, those who:

- Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged);
- Lack comprehension of the research and its risks (e.g., educationally disadvantaged, dementia, schizophrenia, or depression);
- Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault); and
- Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).
Applicable Regulations and Documents:
21 CFR 56.111(b) Additional Safeguards
45 CFR 46.109(e) IRB review of research (consultants)
45 CFR 46.111(b) additional safeguards required
45 CFR 46 Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
45 CFR 46 Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
45 CFR 46 Subpart D: Additional Protections for Children Involved as Subjects in Research
http://answers.hhs.gov/ohrp/questions/7226: OHRP Frequently Asked Questions: How to the regulations define "prisoner"?
VHA Handbook 1200.5, Appendix D
HRPP Policy II.01 Obtaining Informed Consent in Human Subject Research
HRPP Policy III.01: Review of Human Subjects Research by the Institutional Review Board
HRPP Procedure 201 Writing an Informed Consent Document for Human Subject Research
HRPP Procedure 204 Obtaining Informed Consent in Human Subject Research
HRPP Procedure 301: Administrative Pre-Review of Research Submissions, Initial Determination of Review Type and Assignment of Reviewers
HRPP Procedure 305: Inviting Consultants to Review IRB Protocol Documents
HRPP Procedure 331 Institutional Review Board Review of Research Involving Prisoners
HRPP Procedure 332 Institutional Review Board Review of Research Involving Minors
HRPP Procedure 333 Institutional Review Board Review of Research Involving Cognitively Impaired Individuals
Protecting Vulnerable Populations in Human Subject Research
Adopted: 11/2005 Revised: 03/2015

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<td>11/2005</td>
<td>L. Harpster</td>
<td>11/2006</td>
<td>AAHRPP requirement</td>
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<td>07/2009</td>
<td>J. Gerlach</td>
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<td>Background section revised to include reference to Policy V.07 <em>Individuals with a Psychiatric Diagnosis Who Are Able to Consent But May Be Vulnerable to Coercion</em></td>
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<td>06/2014</td>
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<td>Major revision so this Policy refers to vulnerable populations in general, moving details about specific populations to new HRP Procedures</td>
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Date Adopted  **March 2015**  Signature  _signed copy on file_