SOP 1.4.4 **Research Involving Other Vulnerable Populations**

General Description:

Research activities at GMU involving humans must undergo some level of ethical review by the IRB office or the IRB. Research involving potentially vulnerable populations such as students, employees, and adults with impaired decision-making capacity may require additional protections since they may be vulnerable to coercion or undue influence because their autonomy is limited in some way, which may affect their ability to provide voluntary informed consent. This policy does not include a comprehensive list of potentially vulnerable participants and researchers should contact the IRB office if they have questions about whether or not the population they are studying might be considered vulnerable.

Policy:

1. Human subjects regulations state that IRBs "should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons."
2. The federal regulations do not provide specific criteria to be applied for vulnerable populations other than prisoners and children. Therefore, the IRB must make case-by-case decisions on when a proposed research population may constitute a vulnerable population.
3. When the IRB regularly reviews research that involves vulnerable participants, the IRB membership will include one or more members who are knowledgeable about the proposed research populations. The IRB may also request assistance from expert consultants during the review of research involving vulnerable populations.

Procedures:

1. If a research project involves a vulnerable subject population, the researcher must include this information in the applicable sections of the IRB application and complete Addendum H (Other potentially vulnerable populations) describing any special recruitment and consent processes that will be used to ensure that the subjects understand the research study.
2. If the research participant has diminished decision-making capacity, the researcher should include information about how he/she will assess the participant's capacity to consent for him/herself. If the participant is not able to consent for him/herself, the researcher should include information about how consent will be obtained from the participant's Legally Authorized Representative (LAR) and how assent will be obtained from the participant (when appropriate).
3. Template assent forms are available in IRBNet that can be used for participants with diminished capabilities.
4. The IRB will review the protocol in accordance with 45 CFR 46. The IRB will complete the checklist for research involving other vulnerable populations, which will ensure that any applicable regulatory requirements for research involving the vulnerable population have been met.
5. The IRB will determine that the researcher describes adequate provisions for determining the consent capabilities of the participant and for soliciting the consent of either the participant or the participant's LAR.
6. The IRB will follow regular procedures for an exempt, expedited or full board review as necessary.

Related Forms, Guidance, and SOPs:

- IRB application addendum H – Other potentially vulnerable populations
- 1.4.1 Research Involving Children
- 1.4.5 College students as research participants
- 2.2.1 Informed consent, assent, parental permission, and documentation
- 2.5.1 Full board review
- 2.5.2 Exempt and expedited
- OHPR guidance on vulnerable populations: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/vulnerable-populations/index.html
- NIH Guidance "Research Involving Individuals with Questionable Capacity to Consent": https://grants.nih.gov/grants/policy/questionablecapacity.htm

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	May 24, 2017
Laurie Meamber	IRB Chairperson	May 24, 2017