5.0 REVIEWING RESEARCH INVOLVING VULNERABLE SUBJECTS

5.1 OBJECTIVE

To describe policies and procedures for reviewing research involving vulnerable subjects

5.2 GENERAL DESCRIPTION

The Howard University (HU) Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, individuals with *impaired decision-capacity and economically or educationally disadvantaged persons*. The IRB also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation.

5.3 RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Study Personnel, IRB, Office of Research Regulatory Compliance (ORRC) Staff.

5.4 PROCEDURES

5.4.1 Screening and Educational Guidance

- The PI identifies the categories of vulnerable subjects (e.g., individuals with *impaired decision-capacity*, children, prisoners, students, *and economically or educationally disadvantaged persons*) involved in the research in the IRB application (e.g., Inclusion/Exclusion Criteria discussion in the Research Description).

- When research on vulnerable subjects is conducted outside the Washington, D.C. area, the PI identifies the state law(s) applicable to the determination of legally authorized representative and contacts HU legal counsel for review and determination prior to approval by the IRB. If the PI is unable to identify applicable *state, local or tribal law(s),* the PI contacts HU legal counsel for assistance prior to approval by the IRB.

- In addition, the investigator completes specific forms in the IRB initial review application which focus on ethical and regulatory issues pertaining to conduct of research involving neonates, fetuses, prisoners, children, and individuals with impaired consent capacity.

- Upon receipt of an IRB application, ORRC staff conducts a preliminary screening. When applicable, ORRC staff provides Protocol Specific Training (PST) materials to the IRB on the regulations pertaining to vulnerable subjects as outlined in the Initial Full Review and Expedited Initial Review SOPPs.

- The ORRC, IRB Chair, or designee requests a consultant review if additional expertise is needed (See Initial Full Review, Expedited Initial Review, Continuing Review, or Modification, Deviations, and Exceptions-IRB Review of Changes SOPPs).

- IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children or prisoners. ORRC staff screen the application to ensure that designated representatives review research involving children or prisoners. Depending upon the type of review, designated representatives either attend the convened meeting or provide comments in writing.

5.4.2 Protocol Review Process

- The IRB reviews the IRB application to determine whether the study protocol includes enrollment of vulnerable subjects and whether appropriate safeguards are in place.

- As applicable, the IRB considers the following elements when reviewing research involving vulnerable subjects:
  - Inclusion/exclusion criteria;
  - Over-selection or exclusion of certain groups based on perceived limitations (i.e., targeting prisoners as research subjects because they are a readily available “captive” population);
  - Knowledge of applicable *local and or tribal laws* that bear on the decision-making process (i.e., emancipated individuals, legally authorized representatives, age of majority for research consent).

- The IRB follows applicable federal and state regulations and IRB policy to assist in reviewing and approving proposed research that involves vulnerable subjects such as:
  - Human Fetuses and Neonates (45 CFR 46, Subpart B)
  - Research Involving Prisoners (45 CFR 46, Subpart C)
  - Research Involving Children (45 CFR 46, Subpart D, 21 CFR 50, Subpart D and U.S. Department of Education, Subpart D)
  - Research Involving Individuals with Impaired Consent Capacity – (See the Informed Consent SOPP);

- Research involving HU students – (See the IRB Guidance for Enrolling University Students as Subjects);
- Research involving K-12 students – (See the IRB Guidance for Enrolling Minors).

- The IRB considers each of the specific findings discussed in the IRB application forms for research involving vulnerable subjects, as documented by IRB approval. IRB approval also documents that the IRB members acknowledge and agree with the preliminary description of safeguards and risk assessment of the protocol as described in the application by the PI. ORRC staff document in the minutes discussions of controverted issues at convened meetings.

- ORRC staff document specific findings in the meeting minutes, or exempt/expedited reviewers document determinations in accord with applicable IRB/ORRC SOPPs. The IRB does not reapply the categories during subsequent reviews unless changes to the protocol dictate otherwise.

- The IRB may require review more frequently than once a year for protocols involving vulnerable populations based on the nature of the research and the level of risk.

5.5 REFERENCES

45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
21 CFR 50 Subpart D
34 CFR 97 Subpart D