"(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, [handicapped, or] mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.” 45 CFR 46.111, 21 CFR 56.111 [FDA]

Institutional Review Board (IRB) members should evaluate research studies to determine what, if any, vulnerable populations will be included in the research population. Vulnerable populations include, but are not limited to, children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. If the research population does include vulnerable populations, IRB members should evaluate whether additional safeguards are necessary to protect these subjects. If the investigator has included additional safeguards, the IRB members should evaluate whether the safeguards are adequate.

Additional provisions of the federal regulations governing human subjects research also govern research and related activities involving pregnant women, human fetuses, and neonates, (45 CFR 46 subpart B), prisoners (45 CFR 46 subpart C) and children (45 CFR 46 subpart D; 21 CFR 50 subpart D).

**Additional Considerations**

For policies and procedures on certain vulnerable populations, see the following sections of the Human Research Protection Program (HRPP) Manual:

- **6-8-A**  Pregnant Women, Human Fetuses and Neonates
- **6-8-B**  Prisoners
- **6-8-C**  Children and Minors
- **6-8-D**  Individuals with Diminished Capacity
- **6-8-E**  HIV and AIDS

For research studies subject to the requirements of the U.S. Department of Education or the International Conference on Harmonization Good Clinical Practice (E6), see the following sections of the HRPP Manual:

- **2-2-D**  U.S. Department of Education
- **2-4**  International Conference on Harmonization Good Clinical Practice (E6)