VULNERABLE POPULATIONS

a. **Children** – All studies involving children which are not otherwise exempt require IRB review in accordance with the provisions of 45 CFR 46 subpart D, Additional Protections for Children Involved as Subjects in Research.

i. For children between 7 to 18 years, documented assent of the child and informed consent of the parent or guardian are required, and research involving greater than minimal risk must present the prospect of direct benefit to the individual subjects.

ii. Research involving **children**, although designated a "vulnerable population," can be classified as Exempt from review under most conditions. All exempt categories apply to research with children except parts of category 2: observations of public behavior involving children may be exempt when the investigator(s) do not participate in the activities being observed. However, research with children involving survey or interview procedures may not be exempt from review.

iii. Research involving **children**, although designated a "vulnerable population," can be classified as Expedited Review if the study fulfills the general criteria.

iv. Contact the IRB Administrative Office for specifics, or view the Office of Human Research Protections' (OHRP) website for additional information.

b. **Pregnant women or fetuses** - Research involving pregnant women or fetuses which are not otherwise exempt require IRB review in accordance with the provisions of 45 CFR 46 subpart B, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research.

i. Research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates, although designated a "vulnerable population," can be classified as Exempt from review when the study meets the criteria of one or more of the categories.

ii. Research involving pregnant women or fetuses are restricted. Specific conditions concerning assessing potential risks and obtaining informed consent apply. Contact the IRB Administrative Office for restriction specifics or refer to the Office of Human Research Protections' (OHRP) website for more information.

c. **Prisoners** – Research involving prisoners requires IRB review in accordance with the provisions of 45 CFR 46 Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

i. When no more than minimal risk and no more than inconvenience to the subjects, investigators may study the possible causes, effects, and processes of incarceration, and of criminal behavior; or study prisons as institutional structures or prisoners as incarcerated persons.

ii. Investigators may conduct research on practices with the intent and reasonable probability of improving the health or well-being of the subject.

iii. Studies may not be approved which require assignment of prisoners to control groups which may not benefit from the research.

iv. Research on conditions particularly affecting prisoners as a class requires additional consultation with appropriate experts including experts in penology, medicine, and ethics.

v. Contact the IRB Administrative Office for specifics, or view the Office of Human Research Protections' (OHRP) website for additional information.

PROTECTED POPULATIONS

- **Representative from a minority group** - Subject selection is from individuals considered to be representative of a minority group. A minority group is any category of people that is set apart by physical or cultural difference and socially disadvantaged as a result. Minority group does not refer to a numerical minority.
- **Institutionalized People**: Informed consent is problematic and the subjects are vulnerable. Contact the IRB Administrative Office for restriction specifics.