Title: SARMC Institutional Review Board: Vulnerable Populations

Policy Statement: The Code of Federal Regulations at 45 CFR 46.111(b) and 21 CFR 56.111(b), requires IRBs to give special consideration to protecting the welfare of vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

The term 'vulnerable' is a person who is more at risk to have compromised autonomy as it relates to decisions about participating in a research study. The IRB is concerned about respect for persons. In vulnerable populations additional protections are necessary. Vulnerable populations may be more at risk for exploitation and coercion (undue influence). Additional steps and procedures may need to be executed to assure that a vulnerable participant has volunteered to participate in a research project and that the capability to refuse participation is attainable. The IRB is required to include adequate representation on the Board when considering specific kinds of research involving vulnerable populations.

Procedure:

I. Elements to Consider: The research proposal/protocol needs to address the following:

A. Inclusion and exclusion criteria for selecting and recruiting participants must be defined and justified.

B. The informed consent process must be detailed and address how voluntary participation will be assured, list steps that will be taken to eliminate coercion and undue influence, and detail how confidentiality of data will be assured.

C. Without adequate justification in the protocol/research proposal, investigators will not be permitted to over-select or exclude certain groups based on perceived limitations or complexities associated with those groups. For example, it is not appropriate to target prisoners as research subjects merely because they are a readily available “captive” population.

D. When it deems necessary, the IRB will obtain information regarding laws and science that bear on the decision-making capacity of the potentially vulnerable populations to be involved in the research.

E. Just as in providing medical care, research studies that involve potentially vulnerable populations must have adequate procedures in place for assessing subjects’ capacity, understanding, and informed consent or assent.
F. In certain instances, the IRB may require researchers to enhance understanding for potentially vulnerable subjects. Examples include the inclusion of a consent monitor, a subject advocate, interpreter for hearing-impaired subjects, translation of informed consent forms into languages the subjects understand, and reading the consent form to subjects slowly to gauge their understanding paragraph by paragraph.

G. Under certain circumstances, the IRB may require that the investigator submit each signed informed consent form to the IRB, that someone from the IRB or independent participant advocate oversee the consent process, or that a well-defined waiting period be established between initial contact and enrollment to allow time for family discussion and questions. Extra protections may need to be in place to eliminate harm to the participant.

II. The IRB must have a representative from the vulnerable population participate in the study review. This may result in a longer review period than usual. The principal investigator is encouraged to contact the Office of Research Integrity if and when they are planning to submit a proposal involving vulnerable populations as subjects.

**Related Policies:** Vulnerable Populations - Children; Vulnerable Populations - Decisionally Impaired and Other Potentially Vulnerable Subjects; Vulnerable Populations - Research Involving Prisoners; Vulnerable Populations - Pregnant Women, Human Fetuses, and Neonates

**Related Forms:** None

**References:**

Code of Federal Regulations. (Last revised January 15, 2010). Title 45A – Department of Health and Human Services; Part 46 – Protection of Human Subjects; Subparts B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research); C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects); and D (Additional Protections for Children Involved as Subjects in Research)