1.0 Purpose
The purpose of this SOP is to describe additional protections for vulnerable populations.

2.0 Policy
It is the policy of the IRB that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with Health and Human Services regulations at 45 CFR §46.111(a)(3).

Health and Human Services regulations at 45 CFR §46 provide special protections for prisoners (Subpart C) and children (Subpart D). 45 CFR §46 does not, however, include specific requirements for the protection of other vulnerable participant populations, such as decisionally impaired persons, terminally ill, economically or educationally disadvantaged persons, or other vulnerable populations. In these situations, the IRB, in consultation with the investigator, will determine the appropriate means to protect the rights and welfare of the individuals.

2.1 Definition
A. Vulnerable population is defined as an individual or group of individuals with limited autonomy (e.g., lacks independence in decision making for a variety of reasons) or is otherwise at increased risk compared to non-vulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

2.2 Categories of Vulnerable Populations
Vulnerable populations may be categorized according to the following groups:

A. Prisoners (Subpart C) (see HRPP policy # 5.003)
B. Children (Subpart D) (see HRPP policy # 5.004)
C. Pregnant women (Subpart B) (see HRPP policy # 5.002)
D. Fetuses and neonates (Subpart B) (see HRPP policy # 5.002)
E. Decisionally impaired (see HRPP policy # 5.002)
F. Comatose
G. Terminally ill
H. Economically disadvantaged
I. Educationally disadvantaged
J. Socially disadvantaged
K. Employees and students (see HRPP policy # 5.006)
L. Others as determined by the IRB and investigator

2.3 Factors Determining Vulnerability
A. The nature of the research.
B. The risks of the research.
C. An increased probability of risk occurrence in the proposed population.
D. Degree of autonomy, or limited autonomy, present in the proposed population.
E. The clinical status of the proposed population.
F. The educational status of the proposed population.
G. The economic status of the proposed population.
H. The presence of a support system (e.g., family and friends) for the proposed population.
I. Cultural or social factors associated with the proposed population.

2.4 Additional Protections for Vulnerable Populations
Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by HRPP policies for research involving pregnant women, prisoners, children, or decisionally impaired participants.

Other additional protections, as deemed necessary by the IRB, may also be included:
A. The use of an extended consent process.
B. The use of a consent monitor.
C. Appointment of a participant advocate.
D. Involvement of the participant’s family and/or friends.
E. Limits placed on risk.
F. Exclusion from participating in the research.
G. Increased safeguards to protect privacy and confidentiality.
H. Increased monitoring of the research by the IRB or other mechanisms.
I. More stringent withdrawal criteria.
J. Longer study follow-up.

Administrative Approval:

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