SOP 5.07 Additional Decisions Available to the IRB (options for equivalent protections)

1. Objective
In accordance with 45 CFR 46.111(3), the IRB ensures that the selection of subjects is equitable and gives special consideration to protecting the rights and welfare of vulnerable populations. The purpose of this SOP is to discuss general options available to the IRB for implementing accommodations when some or all of the desired study subjects are considered vulnerable.

2. General Description
There are three main considerations for determining if the selection of subjects is equitable: study purpose, research setting, and special problems where vulnerable subjects are involved. The IRB must consider whether the subjects selected to participate are members of the population most likely to benefit from the research, and then also whether the additional burdens of participating in the research are justified given a subject populations' vulnerable status. The IRB outlines any special accommodations for noted vulnerabilities to help ensure adequate protection of subjects.

*Vulnerable population* - means an individual or group of individuals who may be relatively or absolutely incapable of protecting their own interests, and where different levels of vulnerability based on capacity, circumstance, or condition affect independent decision-making and/or where their willingness to volunteer for research may be unduly influenced. This may include, but is not limited to, children, prisoners, pregnant women, fetuses/neonates, economically or educationally disadvantaged, cognitively impaired individuals, employees, elderly, or students.

3. Roles & Responsibilities
Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

**Principal Investigator (PI)**
A PI may be required to submit additional application forms and/or materials depending on the desired subject population(s), and/or research activities. Additionally, a PI may be required to establish or modify study procedures to accommodate subject vulnerabilities.

4. Procedures
First and foremost, consideration shall be given during the IRB review toward utilizing one or more IRB members who are knowledgeable about and experienced in working with the desired subject population. The IRB may procure, for the purposes of providing expertise or special knowledge surrounding a topic
or issue of concern, an outside consultant(s) to advise an IRB review of a protocol or IRB related request. The consultant will serve in an advisory role only, is not a voting member of the IRB and will not be counted toward quorum. Any consultant(s) will be asked to provide acknowledgment that the review of study or study related materials are of a private nature, and that confidentiality of any shared information will be maintained.

The reviewer(s) will closely evaluate the study population, whether or not the population is reasonably related to the purpose of the research, the specific inclusion/exclusion criteria, and justification for the inclusion/exclusion criteria.

The reviewer(s) will informally establish a subject vulnerability profile. General factors that may be considered are, the nature of the research, the risks of the research, any increased probability of risk occurrence in the proposed population, the populations’ degree of autonomy, or limited autonomy, the populations’ clinical status, the populations’ educational status, the populations’ economic status, the presence of any support systems (e.g., family and friends), cultural or social factors associated with the proposed population.

Whenever possible, the IRB will seek to determine if the research is designed for a situation or condition relevant to the vulnerable population, and whether or not the objectives of the research can be met by conducting the research in a population that does not have the noted vulnerabilities.

Whenever possible, the IRB will seek to establish that the research is either minimal risk, more than minimal risk with a prospect of direct benefit, or more than minimal risk without a prospect of direct benefit, but of vital importance to the vulnerable population.

The IRB will outline accommodations for any noted vulnerabilities that may include, but are not limited to:

- Additional and/or modified subject inclusion/exclusion criteria.
- Additional and/or modified consent procedures. For example, use of a verbal consent script in addition to a written form, and/or periodic re-affirmations for select study procedures.
- Involvement of the participant's family and/or friends during the consent process and/or research activities.
- Use of a consent monitor.
- Use of a subject advocate.
- Additional requirements/safeguards for protecting privacy and confidentiality.
- Increased study monitoring procedures, possibly by an independent party.
- Additional and/or modified subject withdrawal procedures.
- Extended participant follow-up.
- Continuing review more frequently than once a year.

The IRB will determine special accommodations for vulnerable subjects on a case by case basis taking into account the risks and benefits of the study over all, and other protections that may be in place. The IRB may consider any additional accommodations as part of the criteria for approval of a study or study action.

5. References

45 CFR 46.111
45 CFR 46, Subparts B, C, D  
Institutional Review Board Management and Function, Bankert & Amdur – Chapters: 5-3, 9-1  
SOP 7.01 – Vulnerable Subjects: Children  
SOP 7.02 – Vulnerable Subjects: Prisoners  
SOP 7.03 – Vulnerable Subjects: Pregnant Women, Human Fetuses, and Neonates  
SOP 7.04 – Vulnerable Subjects: Wards of the State  
SOP 7.05 – UNLV Students as Research Subjects  
SOP 7.07 – Vulnerable Subjects: Economically Disadvantaged  
The National Bioethics Advisory Commission (NBAC) analytical framework for identifying subject vulnerability