SOP 7.07 – Vulnerable Populations –Economically Disadvantaged

1. Objective

To describe the procedures for consideration toward special safeguards needed in research studies when recruiting and enrolling persons who are economically disadvantaged.

2. General Description

Participation in research by members of economically disadvantaged groups is often essential to ensure that research findings can be of benefit to all persons at risk of the disease, disorder or condition being studied. Special attention may be needed to ensure that any possible coercion or undue influence is mitigated to the extent possible.

Safeguards must be in place during the entire research relationship to ensure open and free communication between the researcher and the prospective subject. Consent documents must be written in language that is easily understandable to subjects; the possibility of illiteracy should be accounted for, as should the need for communicating in other languages. The informed consent documents should be available in English and other languages as appropriate to the subject populations.

3. Roles & Responsibilities

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

Investigators

Due to the financial restraints that may exist among this population, the Investigator must ensure that compensation is commensurate with the risk, discomfort or inconvenience involved in the research. The Investigator must pay special attention to recruitment processes occurring in institutional or other settings to insure that voluntary participation is not compromised. The Investigator must take care to insure that any other special needs of this population are adequately addressed. Such special needs may include child care and transportation. Additional features include, but are not limited to, the amount and form of compensation, the anticipated literacy level of the subjects, and possible safety factors contingent on where and by whom the study will be conducted.

Investigators, particularly those who have not previously conducted approved studies with this population, are encouraged to arrange a meeting with ORI-HS staff during the early planning stages for the study for guidance about special features of such studies.

IRB

The IRB must review recruitment and informed consent materials, and carefully consider any language that may promise "free" treatment or otherwise draw unreasonable attention to care or gain that subjects may receive during the research. The IRB must confirm that the roles of the Investigator noted above have been satisfactorily addressed. The IRB may wish to involve representatives from the target populations for consultation during review.

ORI-HS

ORI-HS may be asked to provide assistance to the IRB to identify consultants familiar with the cultural context in which the proposed study would be conducted.

4. Procedures

The IRB shall determine that adequate provisions are made for soliciting informed consent where appropriate (See SOP 6.01). The IRB shall discuss and help determine that any special needs, as discussed above, are adequately addressed by the study protocol and where appropriate.

The consent process and associated document(s) approved for use will be documented in the ORI-HS study file. A stamped informed consent document(s) with the IRB approved protocol number and study expiration date will be issued to the Principal Investigator upon approval.

5. References

45 CFR 46.116
21 CFR 50.20
SOP 6.01