MCW Office of Research
Standard Operating Procedure

RESEARCH INVOLVING ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
When conducting human subjects research with economically or educationally disadvantaged persons, additional safeguards must be in place due to the unique concerns of that population, including potential vulnerability to undue influence or coercion.

The MCW IRB reviews and approves research involving economically or educationally disadvantaged subjects in compliance with the Common Rule and other applicable regulations and laws.

DEFINITIONS:
Economically disadvantaged: Economically disadvantaged persons may struggle to meet their daily necessities for themselves or their families. These individuals may be especially vulnerable to offers of medical care, remedial education, or financial incentives.

Educationally disadvantaged: Educationally disadvantaged persons may have educational deficits or learning disabilities that limit communication with the research team. These individuals may have issues understanding the consent process or may have issues that prevent them from completing survey or from performing written instructions. These educational deficits may not be immediately apparent to researchers.

PROCEDURE:
1. It is the responsibility of the Investigator to be aware of the potential for enrolling vulnerable subjects into their research project and identifying appropriate safeguards when vulnerable subjects are the focus of their research.

2. Investigators must identify in their eBridge SmartForm when their research project will include economically or educationally disadvantaged subjects.

3. Researchers seeking to conduct research with economically or educationally disadvantaged subjects must ensure appropriate safeguards are in place to minimize coercion or undue influence, including, but not limited to, the following:
   - Incentives should be commensurate with the risks and discomforts of the study, along with the time and inconvenience. Incentive should not be overly

compelling such that an economically or educationally disadvantaged person would choose to participate when otherwise they would not.

- Recruitment materials should not offer “free” treatment or over-emphasize the medical care that will be received during treatment.
- Recruitment processes must be carefully designed to ensure that participation is truly voluntary.
- Safeguards should be in place during consenting and throughout the study to ensure that communication is free and open between the prospective subject and the research team.
- Consent documents must be written in a language that is easily understandable to the prospective subject.
- As it is possible that some subjects may be illiterate or have limited reading skills or may have a need to communicate in a foreign language, the study team must pro-actively consider and address these needs.

REFERENCES:
IRB SOP: Informed Consent for Human Subject Research
IRB SOP: Recruitment and Enrollment of non-English or Limited English-Proficient subjects

SUPPORTING DOCUMENTS:
N/A

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