



## RESEARCH INVOLVING ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED INDIVIDUALS

### Definitions

**Common Rule:** The Federal Policy for Protection of Human Subjects found in HHS regulations in 45 CFR 46 includes four subparts. Subpart A is also known as the “Common Rule” applies to human subjects research conducted or supported by federal agencies that have adopted the regulations.

**Economically or Educationally Disadvantaged Individuals:** Individuals who are placed at special risk by virtue of their socioeconomic and/or educational background. As research participants, these individuals may be vulnerable to coercion or undue influence.

### Federal Research Regulations

In order for the IRB to approve research, federal regulations require that the selection of participants is equitable. When making this assessment, the IRB must be particularly cognizant of research involving populations vulnerable to coercion or undue influence. Among the groups listed in Subpart A are persons who are economically or educationally disadvantaged.

### Description

As the IRB considers research involving economically or educationally disadvantaged individuals, emphasis is placed on the protections that the researcher will provide in order to diminish or eliminate coercion or undue influence. Investigators are expected to indicate whether the study may include economically or educationally disadvantaged individuals and describe the proposed efforts to protect them. The IRB may require that the investigator adjust planned protection processes in order to best ensure appropriate safeguards are in place to preserve the rights and welfare of this population.

#### *Considerations for Voluntary Participation*

Medical care and financial remuneration are common inducements in research. Therefore, care must be taken to ensure participant incentives are commensurate with the risks, discomforts, and inconveniences involved. To a person who is economically disadvantaged, seemingly nominal incentives may be strongly coercive. Those lacking in financial or medical resources may be likelier to participate in studies of greater risk when participation is associated with medical care or significant compensation. Even trials offering an otherwise fair level of compensation can be coercive to individuals with limited economic resources.

Financial, medical, or other gains may not be so compelling that they unduly influence an individual’s choice to participate in research. Recruitment materials must not promise free treatment or overly emphasize the medical care participants receive during research participation. Recruitment materials must be written at a level that can be easily understood by the population.

#### *Considerations for Informed Consent*

Educationally disadvantaged persons may have educational deficits, learning disabilities, or cultural backgrounds that limit communication with research staff and investigators. It is the responsibility of the investigator to ensure that a participant is fully informed. This includes presenting material at an appropriate level, in the appropriate language, and using an appropriate medium (e.g., verbal or visual). Safeguards should be in place to ensure participants are adequately informed to make decisions about research participation.

### Additional Considerations

There is potential that those who are economically or educationally disadvantaged may also represent another vulnerable population requiring additional protections (e.g., wards of state, individuals with cognitive impairment, etc.). Additional

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considerations and requirements are associated with the inclusion of vulnerable populations such as children, wards of state, prisoners, etc. Additional information may be found on the IRB website.

## Points to Address

### ERICA Application:

- 1. Participants Page, Vulnerable Population:** Select “Other” as a participant population. Specify economically disadvantaged individuals, educationally disadvantaged individuals, or both as applicable. It is acceptable to insert a specific population, e.g., “homeless individuals”.
- 2. Vulnerable Populations Page:** Justify the inclusion of this population, including whether the population is being targeted specifically due to the requirements of the study. Are you including these individuals for specific reasons?
- 3. Risks and Benefits Page, Compensation:** Consider the amount of monetary compensation associated with this research given the needs of this vulnerable population. Describe the foreseeable risks and benefits to the participants, taking into account the participants’ situation and ensuring that any potential benefits are not coercive.
- 4. Consent Process Page:** Please describe any specific processes that will be used to obtain consent from individuals who may be economically or educationally disadvantaged.

## References & Links

*Basic HHS Policy for Protection of Human Research Subjects (OHRP): 45 CFR 46 Subpart A*

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb>

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