University of Kentucky IRB Guidance on Research Involving Economically or Educationally Disadvantaged Persons

The revised common rule outlines additional considerations and concerns in the enrollment of economically or educationally disadvantaged persons. The inclusion of participants representing a variety of social and economic backgrounds is crucial in ensuring that research findings benefit and are reflective of all individuals who may be affected by the disease, disorder, condition, etc. being studied.

The following criteria for IRB approval outline the minimum expectations when including this population in research:

45 CFR 46.111 Criteria for IRB approval of research

- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or *economically or educationally disadvantaged persons*
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or *economically or educationally disadvantaged persons*, additional safeguards have been included in the study to protect the rights and welfare of these subjects

Concerns and Considerations

Economically or educationally disadvantaged persons may be subject to undue influence in participating in research due to limited understanding and/or unfair level of benefit in exchange for study participation (perception of free treatment, access to treatment, or compensation). As with all research, the benefits and risks must be weighed and evaluated to ensure the ethical conduct of a study. For the inclusion of economically or educationally disadvantaged persons, the benefits must not be so great that the subjects disregard the risks. Alternatively, the benefits of participation in comparison to the risk, must not be so minimal such that only those who are economically or educationally disadvantaged want to participate. Studies should not be skewed toward either extreme.

Researchers and IRB reviewers must carefully consider the population and take precautions in developing and reviewing research studies to ensure a given study does not unduly influence this population to participate and is not exploitive. The following table provides a brief outline of concerns, safeguards, and additional considerations and suggestions. The table should be viewed as broad guidance and not a comprehensive listing, as each study is unique and may require additional safeguards or processes.

Concerns	Safeguards	Additional Considerations and Suggestions
Subjects may enroll in research without fully understanding study risks	• Subjects may have limited health literacy and numeracy so consent documents must be written in language that is easily understandable and appropriate for the population. • Study staff must assess understanding and facilitate an ongoing dialogue. • The possibility of illiteracy or limited reading ability must be accounted for and plans to address this put in place for both the consent document and consent process.	Documents: • Refer to ORI Tools for Developing Informed Consent Documents for plain language toolkits and lay term resources. Process: • Always use teach back techniques to assess understanding and clarify misperceptions. • Refer to the UK Guidance on Unique Informed Consent Circumstances for process options for subjects with literacy limitations including Verbal Consent Process with impartial witness.
Rewards/services or compensation may be unduly influential	• Incentives for participation in research must be commensurate with risks, discomforts, burdens, and inconveniences involved. • Compensation should not be overly compelling. • The proposed method and timing of disbursement should not present undue influence. • Because influence is contextual, and undue influence depends on the individual situation, the investigator should evaluate potential during the consent process. • Where a potential participant's judgement is impaired by incentives or the hope of benefit and he/she does not appreciate potential risks, consent may not be valid.	• Recruitment material should not advertise "free" medical treatment; instead, "compensation provided" can be listed • Incentives should not be contingent upon study completion; listing a partial payment schedule is permissible. • Alternate therapies/treatments should be adequately explained. • Consistently practice a consent process that begins with two-way communication to evaluate the potential subject's knowledge base, perceptions, and motives. • Ask questions to assess undue influence during the consent process. • Refer to the Investigator's Guide to Identification and Recruitment of Human Subjects for payment guidance.
Unfair level of benefit in exchange for participation by result in exploitation (high risk; few benefits)	• Benefits should be appropriate for the risks involved and should not cause inequitable subject selection. • Receipt of treatment/placebo should be provided in equal opportunities across socioeconomic statuses. • Benefits must be considered fair for all individuals involved.	• Even if the benefits are deemed fair, whether the study is exploitative by its nature should be considered. • As recruitment occurs, study teams can self-assess whether economically and/or educationally disadvantaged persons are enrolling disproportionately and make adjustments accordingly.

Additional Resources

- Clinical research with economically disadvantaged populations https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2598135/
- Enrollment of Economically Disadvantaged Participants in Clinical Research https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-06/pfor1-0901.pdf
- A Principal Investigator's Guide to Identification and Recruitment of Human Subjects for Research https://www.research.uky.edu/sites/default/files/uploads/2018-06/7-Recruitguidance.pdf
- UK Office of Research Integrity Guidance on Unique Informed Consent Circumstances https://www.research.uky.edu/uploads/ori-d1350000-guidance-unique-informed-consent-circumstances-pdf
- Paying Subjects to Take Part in Research: A New Perspective on Coercion and Undue Influence https://acrpnet.org/2019/03/12/paying-subjects-to-take-part-in-research-a-new-perspective-on-coercion-and-undue-influence/?utm_campaign=News&utm_medium=email&utm_source=internal&utm_content=CR-Announcement-03152019&utm_term=text-readmore&_zs=rGCCX&_zl=P2fW1