



Criteria for IRB approval of research #3: Selection of subjects is equitable. (§46.111(a)(3))

- “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.”

This criterion is based on the **Belmont Report’s principle of justice**:



- No one group should be targeted or excluded from research without sound scientific or ethical rationale
- Benefits and burdens should be fairly distributed
- Ensure subjects are not “being systematically selected simply because of their easy availability, their compromised position or their manipulability, but rather for reasons directly related to the problem being studied.”

So, what does this mean in terms of the **IRB’s review of the research**?

- **Goal** is to ensure that both benefits and burdens of research are distributed fairly, and that no specific population is being unfairly targeted or excluded.
- The primary consideration in determining who is eligible to enroll is based on the **scientific aims of the study**, so inclusion and exclusion criteria should be based on sound scientific rationale.
- Enrollment of a broad range of eligible subjects will improve **the generalizability of the results**.

In assessing whether the protocol meets the criterion that selection of subjects must be equitable, IRBs should consider these factors and related questions:

Purpose of the research	What is the scientific question that is being asked? Which potential participants will benefit most from the research and can answer the research question?
Inclusion/exclusion criteria	Are the I/E criteria based on the scientific question under study?
Proposed research setting	Has setting been chosen only because it is convenient? Will the location provide access to appropriate participants (those who can help answer the scientific question under study) in an equitable manner? Could the setting be perceived as coercive?
Recruitment methods	Is the recruitment strategy fair? Do the recruitment methods and materials support an equitable selection of participants?
Compensation	Is the compensation fair or could it result in undue influence?
Potential participants who could be considered vulnerable	If participants lack the capacity to consent, is there a scientific necessity to enroll these participants related to the research question? If these potentially vulnerable participants have capacity to consent, could they otherwise be subject to coercion or undue influence?

