

EQUITABLE SELECTION OF SUBJECTS

The regulations governing IRBs require the following as one of the criterion for 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 and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”

As IRB members we must evaluate whether the selection criteria and recruitment practices meet this criterion. In their educational materials, OHRP reminds us “Defining the appropriate group of subjects for a research project involves a variety of factors - requirements of scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. IRBs are required to make a specific determination that the selection of subjects is **equitable**”.

OHRP provides the following example: “Patients may also be susceptible to real or imaginary pressure to participate. If an investigator also serves as a patient's primary physician, he or she may feel obliged to participate in the research out of a desire to please, gratitude, or fear that failure to do so will result in hostility or abandonment. Patients who are dependent upon a particular facility for their care (*e.g.*, Veterans Hospitals, Indian Health Service Hospitals, or community health clinics) may feel that they will be treated less well or with less favor if they refuse to participate in research”.

And finally, OHRP suggests: “With these caveats in mind, investigators and IRBs must be careful not to *overprotect* vulnerable populations so that they are excluded from participating in research in which they wish to participate, particularly where the research involves therapies for conditions with no available treatments (such as HIV). So too, patients with serious or poorly understood disorders may want to participate frequently in research designed to provide a better understanding of their condition. The fact that the subject may be either a patient of the principal investigator or a patient in the clinic or hospital where the investigator conducts the research should not preclude them from the opportunity to choose to participate as often as they wish”.

During our review and assessment of subject selection, we should consider the following issues:

- The purposes of the research.
- The setting in which the research would be conducted.
- Whether prospective participants would be vulnerable to coercion or undue influence.
- The selection (inclusion/exclusion) criteria.
- Participant recruitment and enrollment procedures.
- The amount and timing of payments to participants.

References:

OHRP Guidebook

AAHRPP evaluation tool