

Fair participant selection

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- Exclusion criteria
- Where the study will be conducted
- How the participants will be recruited.

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- Study participants should be chosen so as to minimize risk while maximizing benefits.



- Groups who bear the risk and burdens of research should be in a position to enjoy its benefits and those who benefit should share some of the risks and burdens

- The vulnerability of the study group should be determined.



Limitations to informed consent
comatose persons

Susceptible to coercion or undue influence

critically ill persons

mentally retarded persons

persons with dementias/some psychiatric diseases

individuals who are chronically institutionalized

non-English speaking people

children

the educationally/economically deprived

prisoners

seriously/terminally ill people

paid healthy volunteers



Vulnerable groups

- Can this research be equally well carried out in another less vulnerable group?
- Is the purpose of the research to obtain knowledge relevant to the health needs of this group?
- Are the informed consent or proxy consent procedures adequate?
- Will the prospective subjects' refusal to participate (dissent) be always respected?
- Is there a favourable risk/ benefit ratio?
- Will the group have access to adequate medical and psychological support?
- Will the benefits of the research be made reasonably available to the inhabitants of the vulnerable community?



Fair participant selection

- Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, gender, age, literacy, culture or economic status)?
- Are the inclusion criteria of research participants appropriate to minimize risk while maximizing benefits?
- Are the exclusion criteria of research participants appropriate to minimize risk while maximizing benefits?
- What are the means by which initial contact and recruitment is to be conducted?
- Does the selection of subjects favour any group to have an advantage over others or exclude any group?