



Policy Supporting Document:	E-3.2.4
Policy Holder:	President

the principle of free and informed consent means that only competent individuals should be permitted to participate in research that would likely be harmful or be of no benefit to them. Strict application of such a principle would deny incompetent individuals many of the benefits of research participation, either directly or indirectly. In a sense, such beneficence-based reasoning and practices intentionally exclude certain groups from research. In attempting to avoid the moral problem of exploiting vulnerable research subjects, such practices may incur the moral problem that individuals in need of the benefits of research may be denied them.

Exclusion from research has also arisen indirectly. For example, concerns about legal liability associated with particular populations have prompted the exclusion of women of child-bearing age from drug trials because of possible harms to potential offspring. Further exclusions have been based

1. on concerns about factors such as the effects of the femals be4(t)s about fact65.7m4(s)11(Bo)-4(en)3

2. This statement is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a religious order that is restricted to one sex).
3. Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.
4. Those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals, or to the group that they represent.

The principle of distributive justice inspires the statements above. It imposes a duty on researchers not to discriminate against disadvantaged groups. Groups that have been

