

CONFLICT OF INTEREST

Definition

COI defines as the existence of contradictory interests in relation to any part of the study activity by an individual or institution.

Example

1. The study subject is also your patient under care
2. Researcher are also the stakeholder of the relevant institution
3. Researcher holds a supervisory or administrative post over the potential subjects that may influenced the participatory decision making

What researcher has to do if there is presence of interest?

1. Declare to the JEPPEM
2. Describe the mitigating approach in handling COI

VULNERABLE SUBJECTS

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.