Protection of Vulnerable Populations in Research

In addition to vulnerable subject populations such as **children**, **prisoners**, and **pregnant women** (covered in the subparts of the federal regulations for human subjects research), there are **special classes** of subjects including students, employees, and cognitively impaired individuals who may be vulnerable in terms of their research participation.

Subjects are considered vulnerable when they are not respected as autonomous agents and/or their voluntariness is compromised.

There are two important **types** of vulnerability:

(1) Decisional impairment, whereby potential subjects lack the capacity to make autonomous decisions in their own interest, perhaps as a result of undue influence/inducement

(2) Situational/positional vulnerability, whereby potential participants may be subjected to coercion

The Belmont principle of respect for persons is not upheld when subjects are **unduly influenced**; that is, when they are offered an "excessive, unwarranted, inappropriate, or improper reward" in an effort to secure their participation in a research study. (Just one of many possible examples is offering free health care to individuals with major medical problems and limited resources as an inducement to participate.) Such offers may lead individuals to participate in studies to which they would otherwise have strong objections based on risk tolerance and personal values or preferences. Given that responses to undue influence tend to be highly individual and difficult to predict, it may not be possible to avoid all potential cases. In general, however, IRBs should be vigilant about possible undue influence when studies pose significant risk of harm and offer considerable incentives to participants who have limited means or opportunities.

Whereas undue influence refers to an offer of reward, **coercion** involves an "overt or implicit threat of harm or reprisal" in order to obtain compliance with a request to participate in research. Coercion occurs when someone is in a position to make potential subjects worse off if they don't participate. This power imbalance may very well interfere with a potential subject's capacity to choose or act voluntarily. For example, a provider might threaten to withdraw services unless a client participates in a study, or a student might enroll in a study due to fear of receiving a poor grade in a class. Coercion can also take more subtle forms, such as when workplace culture encourages staff participation in research, and those who decline may be seen as outsiders who are not committed to organizational goals.

There is a number of **safeguards IRBs can recommend** and researchers can employ when studies involve special classes of subjects. For example, where **students** are involved, the instructor (researcher) should arrange to have data collected by an independent third party so that they do not know who participated and cannot access identifiable data until course grades have been assigned. Data collection during regular class meetings should be avoided as loss of instructional time may be considered a loss of benefit. When course credit is issued for research participation, students should have the option to complete an alternate assignment that is comparable in terms of time, effort, and educational benefit.

In work settings, researchers must ensure **employees** understand that participation is not required as a condition of employment. Employees should not be recruited or consented directly by a member of

their current department, and supervisors and peers should not be informed of an employee's decision to participate. When supervisors or administrators are part of the research team, they should only review aggregate data that has been stripped of identifiers.

With regard to **cognitive impairment**, the primary issue is impaired **consent capacity**, which occurs along a continuum in a wide range of conditions and circumstances. Assessments of consent capacity should be tailored to the study population, risk level, and likelihood of involvement of persons with cognitive impairment. Clearly, assessment is critical when studies pose significant risk of harm and there is a strong likelihood that cognitively impaired individuals are included in the sampling frame. Decisions as to whether individuals with known cognitive impairment may be enrolled in a particular study should be based on the extent to which the research questions could be answered by studies involving subjects with *full* consent capacity, and whether the project may contribute to the current or future welfare of the study (cognitively impaired) population. When evaluating the potential risks and benefits of studies where impaired consent capacity may be an issue, IRBs should consider (a) the degree to which the research *introduces* risk, (b) benefits that may be available to subjects only as part of the research, and (c) whether the risk-benefit profile departs from standard care.

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