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HRPO Ethics Series



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Can they volunteer? Coercion and Undue Inducement in the Context of Vulnerability

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Vulnerability

- A fundamental assumption underlies modern clinical research ethics: certain categories of people are presumed to be more likely than others to be misled, mistreated, or otherwise taken advantage of as participants of research. These populations are deemed “vulnerable,” a status that generates a duty for researchers, review committees, and regulators to provide special protections for them (Faden et al. 2004, 44).

Existing regulations

- 1) “Respect for persons”: operationalized in the requirement for an *appropriate* informed consent process.
- 2) “Beneficence”: operationalized in the requirement for a fair risk-benefit ratio.
- 3) “Justice”: operationalized in the requirement for an equitable selection of subjects.

Let's start on the same page. . .

- Point 1: Human subjects regulations (2 and 3) restrict the realm in which people can volunteer (1) for research.
 - You can only volunteer for research within certain limits (minimized risks, favorable risk/benefit ratio, just subject selection, etc.)
- Point 2: Special protections (Subparts B-D) restrict this realm even further.
 - You can only volunteer with permission from parents/research is no more than minimal risk or benefits your population/etc.

Note: This is the basis for human subjects *protections*.

Common question: What about other people who are vulnerable?

- Besides subpart populations (prisoners, pregnant women, children) who else is vulnerable?

What do we do about them?

- Choice 1: Let them volunteer for research like the rest of the population with “special attention”
- Choice 2: Increase formal protections for these groups by adding more subparts.

PRO'S?

CON'S?

Before answering the question, we must distinguish two questions...

1) Are people of a given group vulnerable to research abuses?

VERSUS

2) Are people of a given group vulnerable to research abuses in such a way that they would not be protected under existing regulations (if effectively implemented)?

My suggestion: Only (2) requires special regulations.

Two test cases:



Cognitively Vulnerable

Economically vulnerable

Cognitively vulnerable

- Cognitively vulnerable = lacking “the capacity to deliberate about and decide whether or not to participate in the study (Kipnis 2001, G7).”
- Important note: cognitive vulnerability can be mild or severe, temporary or permanent, contingent or necessary.
- Examples:
 - Lack of education, cultural/language barriers, stressful situations (like illness), dementia, mental illness, brain damage, etc.

Can regulations about informed consent work with the cognitively vulnerable?

- Informed consent requires the subject to be:
 1. Adequately informed
 2. Legally competent and capable of comprehending the information
 3. Capable of a voluntary choice

Can they be informed?

- Already prohibited by regulations:
 - intentionally or inadvertently omitting necessary information
 - misleading information
 - not informing the research subject in a manner, language, or level at which he or she can understand (addressing educational, cultural, temporal, and/or language barriers)
- Key point: these can be *fixed* with appropriate consent process, currently required.

Two options: Protect or enable?

1. Potential participant is not capable of making decisions no matter how/when appropriately information is provided (severe brain injury, persistent dementia, persistent mental illness, etc.)
→ Additional Regulatory protections (protect)
2. Potential participant is temporarily and/or moderately challenged in making these decisions → Existing Protections (enable)

Thoughts? Questions?



Economically vulnerable

- Two categories of harms (Denny and Grady 2007)
 1. Vulnerability to impaired decisionmaking
 2. Vulnerability to exploitation

Impaired decisionmaking (1)

➤ Are economically vulnerable capable of comprehending the study?

If NO

Otherwise. . . Why not?



Question becomes: cognitive vulnerability (1) or (2)

Impaired decisionmaking (2)

- Undue Inducement: Irrationally disregard research risks in light of large incentive
 - example 1: prisoners if offered parole
 - example 2: ill people if offered cure
 - example 3: poor people if offered lots of money

Non research example:

- Project Prevention, US-based organization, offers drug-using women \$300 to undergo surgical sterilization or use long-acting forms of sterilization.
- Ethical or unethical?
- Why?

What is Undue Inducement?

- ➔ While never defined in the U.S. federal regulations, Emanuel defines this concept as a situation where “individuals are offered some good that, *against their better judgment*, makes them assume substantial risks of harm that compromise their welfare (Emanuel 2005, 9).

Is the judgment of economically vulnerable people impaired?

Conceptually, no.

Economic vulnerability \neq educational vulnerability (can be fixed)

\neq inherent cognitive deficits (already
suggested regulations for this)

Therefore, it should not be assumed that economically vulnerable populations are incapable of weighing the situation and choosing the option that is in their best interest.

Empirically, no.

- Bentley and Thacker 2004
- Halpern et al 2004
- Festinger 2005, 2008

Undue Inducement confused with. . .

1. Worry about Economically vulnerable people participating in unreasonably high risk/low benefit research for money or other benefits.

Response:

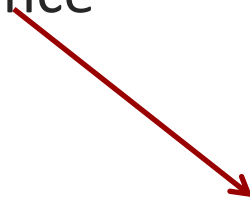
Not irrational choice (in context) , but unreasonable research →
Exploitation

Exploitation

- Exploitation = unfairness in the proportion of risks and benefits to which an individual or population is intentionally exposed by another party.
- Example: Boatman

Exploitation 1: Individuals consent to research with unreasonable risk

- If researchers, through compensation or other goods, shift the risk/benefit calculation so that people accept an unfair risk/benefit balance



Ignored BENEFICENCE regulations: risk/benefit analysis is unfair
(without outside issues)

Exploitation 2: Imbalance of populations of risk and benefit

- if the researcher (or the researcher's company, institution, demographic, or even country) will receive most of the medical, financial, intellectual, and other benefits of the research while the research participants are burdened with supplying the data but receive none or very little of these benefits

Should be weeded out by "Justice" regulations: Fair subject selection.

Important note:

- Existing regulations do NOT address issues of 1) distributive justice or 2) risks and benefits to populations.
- Thus, rather than add a new set of paternalistic protections for the economically vulnerable, the existing “justice” regulations should be widened and improved.

Summary of conclusions:

- ➔ Vulnerability that CANNOT be addressed by current regulations need FURTHER regulations: ie. persistent severe cognitive impairment
- ➔ Vulnerability that CAN be addressed by current regulations needs to focus attention on implementing these regulations WELL.

Thank you.

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